IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

Case No. 1:17-MD-2804
Track One Plaintiffs: Cuyahoga County and Summit County

U.S. District Court for the Northern District of Ohio, Eastern Division

---

EXPERT REPORT OF GREGORY ANDERSON

Date: May 31, 2019

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

Table of Contents

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

I. Introduction and Assignment

1. Plaintiffs in this matter claim that the opioid "*crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors and pharmacies…, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls*."[1] Plaintiffs "*allege that the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain, and distributors failed to properly monitor suspicious orders of those prescription drugs--all of which contributed to the current opioid epidemic*."[2]

2. Defendants in this matter include pharmaceutical manufacturers and distributors (the "Defendants") of prescription opioids such as hydrocodone, oxycodone, and fentanyl. I understand that Plaintiffs in Track One of this matter include Cuyahoga County and Summit County (the "Plaintiffs"). In support of their claims, Plaintiffs submitted expert reports by James E. Rafalski ("Mr. Rafalski") and Dr. Seth B. Whitelaw ("Dr. Whitelaw") on April 15, 2019 ("Rafalski Report"; "Whitelaw Report"). Plaintiffs also submitted an expert report by Mr. Craig McCann ("Dr. McCann") on March 25, 2019 ("McCann Report"), April 3, 2019 ("McCann Supplemental Report"), and later productions by Dr. McCann.

3. I have been retained by Counsel for Walgreen Co. and Walgreen Eastern Co.[3] ("Walgreens") to provide expert testimony regarding DEA regulations in place under the Controlled Substances Act to mitigate diversion of certain Schedule II and III prescription opioids, including oxycodone and hydrocodone, during the timeframe when Walgreens distributed controlled substances.[4] Specifically, I have been asked to provide my professional opinions of Walgreens' compliance with those regulations based on my experience in both an enforcement role with the DEA and an industry compliance role at Amneal Pharmaceuticals.

[1] Corrected Second Amended Complaint and Jury Demand filed May 29, 2018, Doc. #24, p. 5.
[2] https://www.ohnd.uscourts.gov/mdl-2804.
[3] I understand that Walgreens was added as a Defendant in 2018.
[4] When "Prescription Opioids" is used hereafter, it refers to hydrocodone and oxycodone.

LLC ("Amneal"). I have also been asked to respond to the Rafalski Report, Whitelaw Report, and McCann Report as appropriate, including their specific opinions about Walgreens.

4. The facts and opinions expressed in my report are based on my experience, review of publicly available information, review of documents produced in discovery, and review of depositions conducted in this matter.

II. Qualifications and Credentials

5. My unique experience in both government (DEA) and the private sector (Amneal) gives me an in-depth view and perspective on compliance, security of prescription opioids, and federal laws and regulations related to the prevention of diversion of controlled substances.

A. Industry and Enforcement Experience

1. Amneal Pharmaceuticals

6. From April 2012 until July 2018, I was employed as the Vice-President of Drug Enforcement Administration ("DEA") Compliance/Corporate Security at Amneal. In this role, I was charged with enhancing the company's compliance program for controlled substances. To this end, I developed, executed, and promoted an active and robust internal security program, with compliance and security protocols for procuring, handling, shipping/distribution, and storing controlled substances, as well as the implementation of conduct standards and standard operating practices across all of Amneal's eleven U.S. facilities. I also revamped and managed Amneal's Suspicious Orders Monitoring Program ("SOMP"). Amneal held manufacturer, distributor, analytical, and importer/exporter DEA registrations. I ensured that the compliance and security programs conformed with all corporate, federal, and state regulations under the Controlled Substances Act ("CSA"), Code of Federal Regulations ("CFR"), as well as regulations from the US Food and Drug Administration ("FDA") and DEA. This required staying current with changes/updates from the DEA and amendments to the CFR to ensure that the company's policies were up to-date for compliance and regulatory risk mitigation.

7. At Amneal, I served as a Subject Matter Expert on how the DEA functions as an agency, coordinated and oversaw all communications and submissions to DEA and other controlled substances authorities, and represented Amneal during DEA and state inspections. During my leadership, Amneal underwent multiple federal and state site registrations, and licensing inspections. The licensing inspections were carried out by the State of New York and New Jersey. The federal site inspections were carried out by DEA's Offices of Diversion Control in Long Island, New York; Camden, New Jersey; and Louisville, Kentucky. These inspections were the determining factors for yearly approvals of Controlled Substances licensing/registrations, quota allotments, research & development submissions, and import/export permits or declarations.

8. While at Amneal, I implemented a compliance and anti-diversion program for controlled substances. Specific steps undertaken by Amneal to maintain effective controls against diversion included conducting additional background checks and drug screening of employees who worked directly in the DEA Compliance Department; directing DEA compliance training at new employee orientation training, training all employees in how to properly handle and report controlled substances, and educating new hires on the DEA compliance security measure in place; constructing secure vaults, cages, and safes per specifications for safe and secure storage; using access control, alarms, cameras and other surveillance equipment to effectively monitor controlled substances; and securing a reliable transportation service for delivery of raw materials and delivery of finished pharmaceuticals to customers. I also oversaw the DEA Compliance team that directed and administered the Suspicious Order Monitoring Program, quota procurement, license/registrations, import/export permits or declarations, and all site inspections by State and Federal regulators regarding CSA requirements.

2. DEA

9. Prior to my employment at Amneal, I worked for DEA from 1984 to 2012 in various positions, all focused on controlled substances. During my 28 plus years with DEA, over 12 years were in management and/or executive roles within the agency.

10. From 1984 to 1997, I was a Special Agent assigned to the Detroit, Michigan Field Division Office of DEA covering Michigan, Ohio, and Kentucky. From approximately 1984 to 1987, I was assigned to Group III, an enforcement group/diversion response group. One of our responsibilities was to assist Diversion Investigators, who do not have law enforcement authority for enforcement operations.[5] This included investigating rogue practitioners and clinics, controlling confidential informants, assisting in undercover operations, and transporting controlled substances from seizures, surrenders, and arrests. Over this period, I was involved in enforcement operations for pharmaceutical drugs such as Talwin (T's) and blues (antihistamine), Percocet, Dilaudid, and morphine.

11. After 1987, I was a member of the Clandestine Lab Enforcement Team Task Force ("CLET") until 1997. CLET focused on the methamphetamine epidemic and pseudoephedrine List 1 chemicals investigations. In this regard, we investigated pre-cursor chemical movements and clandestine laboratory explosions. In this regard, we investigated pre-cursor chemical movements and clandestine laboratory explosions.

12. From 1997 to 1999, I was selected for a two-year assignment supporting U.S. international operations focused on intelligence gathering and monitoring illicit chemicals used to make heroin. I was based in Lahore, Pakistan, where my duties and responsibilities were to maintain the Diplomatic Mission for the Security and Interest of the U.S. in Pakistan, my role focused on cultivating human intelligence related to illegal acts against the U.S. This included tracking pre-cursor chemicals in-transit from Pakistan to Afghanistan laboratories. I also

[5] Enforcement agents or special agents carry guns, have arrest authority, and investigate all criminal and civil violations of the CSA.

assisted with efforts to educate the local law enforcement counterparts in drug education and eradication.

13. In 1999, I was promoted to Supervisory Special Agent in Detroit, Michigan. I supervised three different enforcement groups from 1999 to 2005: CLET, Homicide Task Force ("Redrum"), and High Intensity Drug Trafficking Areas ("HIDTA"). As a Supervisory Special Agent for these three groups, I led men and women in investigations involving high-risk drug trafficking, drug-related homicides, and clandestine labs/illicit pre-cursor chemicals. My leadership resulted in multiple arrests and successful prosecutions in both federal and state courts. For CLET, my teams continued our enforcement work to combat the methamphetamine epidemic in Michigan, Ohio, and Kentucky through investigations and enforcement. I was then assigned as the supervisor for Redrum, a task force created in response to a high concentration of drug-related homicides that were occurring in the Detroit metropolitan area. The homicides were attributable to highly organized, violent drug-distribution organizations for cocaine, crack cocaine, heroin, and marijuana. The DEA, Detroit Police, and Michigan State Police combined their assets and resources to form the Redrum Task Force to address this problem. I then supervised the HIDTA unit, a task force that included resources from the DEA, Customs and Border Patrol, U.S. Postal Inspection Service, and U.S. Marshall Service, as well as state and local law enforcement. HIDTA units are funded directly by the Office of National Drug Control Policy ("ONDCP") with units located across the U.S. Its mission is to reduce drug trafficking and related violent crimes and money laundering in the HIDTA region. During my tenure, HIDTA focused on crack cocaine high-trafficking areas that most impacted the Detroit metropolitan area.

14. In 2005, I was assigned to DEA headquarters in Arlington, Virginia. As part of career development at DEA, managers were assigned to headquarters to gain a holistic understanding of DEA operations globally. From 2005 to 2007, I served as the Staff Coordinator for Global Enforcement Operations for Europe, Asia, Africa and Canada Section. In this role, I supported DEA offices across these continents and Canada. I provided services for operational funding, travel authorizations, international controlled substance deliveries, and served as the

point of contact for all significant reporting between DEA headquarters and my assigned foreign offices. In Europe, operations were primarily focused on cocaine, heroin, and other illegal controlled substances, with the goal of U.S. prevention. In Canada, the primary focus was pseudoephedrine. In Asia, pre-cursor chemicals and smuggling routes were the primary focus. In Africa, operations were primarily focused on human trafficking (smuggling).

15. From 2007 to 2010, I was the Section Chief of the Organized Crime Drug Enforcement Task Force ("OCDETF") in Arlington, Virginia. OCDETF is the nation's oldest and premier task force that focuses on Consolidated Priority Organization Targets ("CPOTs") and Regional Priority Organization Targets ("RPOTs"), the largest criminal organizations in the world that engage in drug trafficking, money laundering, and human smuggling. Examples of these targets include criminal organizations headed by Pablo Escobar and El Chapo. As Section Chief, I managed and oversaw the DEA's submission for all CPOT- and RPOT-designated investigation requests, ensuring that all CPOT and RPOT requests met specifications and requirements. These requests were submitted to Washington Area Regional Group ("WARG") for approval. WARG included representatives from Department of Justice ("DOJ"), Federal Bureau of Investigations ("FBI"), Immigrations Custom Enforcement ("ICE"), Custom Border Patrol ("CBP"), Internal Revenue Service ("IRS"), U.S. Marshal Service ("USMS"), and United States Coast Guard ("USCG"). Under my direction, my staff managed budgets and serviced all 32 Field Division Offices of the DEA.

16. The last two years of my career with DEA (2010-2012), I was assigned as Section Chief of the Office of Diversion Control, Synthetics and Chemicals ("ODS"). My duties and responsibilities included coordinating, funding, and initiating (national and international) synthetic operations for chemical and pre-cursor chemical movements worldwide. I also oversaw the chemical operations in the 32 DEA Field Division Offices, including trainings and certifications of the DEA Clandestine Lab teams. My duties also included financial and strategic support, communications with the private sector regarding chemical and precursor-related compliance matters (i.e., reviews for importation of List I chemicals and Letters of No Objections), and background investigations of chemical registrant submissions. I briefed Senior

Executive Service management on all progress, significant developments and problems involving chemicals, synthetic compounds, safety, injuries, and related Field Division matters. I also supervised diversion investigators, intelligence analysts, and special agents. At this time, ODS was focused on synthetics used in combination with marijuana (e.g., "spice"). This combination increased the potency and hallucinogenic effects of marijuana. This synthetic drug uses cannabinoids, which were not listed in the schedules of the CSA. I initiated a national initiative, Operation Syn City, to identify, seize, and test various cannabinoid molecules so that they could be added to the listed schedules of the CSA for enforcement operations. During my time with ODS, I achieved the highest performance rating of Outstanding every year, with two Superior Achievement awards.

17. I am also a DEA Certified Instructor/Trainer, DEA Field Trainer, DEA Certified Clandestine Laboratory Investigator, and Assets Forfeiture Financial Investigator. I also received the following awards: DEA Administrator's Award, DEA Exceptional Performance, DEA Sustained Superior Performance, and DOJ OCDETF Regional Case of the Year.

B. Education

18. I earned my Bachelor of Science in Criminal Justice from Kentucky State University in 1980. I also received certification in Strategic Thinking from Johns Hopkins Executive Leadership Institute in 2008 and Executive Leadership from University of Virginia Executive Leadership Institute in 2010.

19. For additional information regarding my qualifications and credentials, please see **Appendix A** to my report. I am being compensated at an hourly rate of $490 for my time in this matter.

III. Summary of Opinions

20. This summary is not meant to replace the detailed opinions I offer throughout my report. It is just a summary, at a very high level, of the topics covered below.

21. Trends in prescription opioid abuse and methods of diversion have changed over time. The DEA's methods of fighting diversion, and of maintaining the closed system of distribution of controlled substances, have also changed over time.

22. Distributors are required to be registered with the DEA to handle controlled substances. Distributors are also required to make good faith efforts to confirm their customers are registered with the DEA. In addition, distributors are required to comply with the suspicious order monitoring and reporting requirements in 21 CFR § 1301.74(b), as well as the other reporting and security requirements under the CSA and its implementing regulations, to track the inventory and movement of Schedule II and III controlled substances. The distributor's role in the closed distribution system for controlled substances is to fulfill orders for legitimate, DEA-registered pharmacies', hospitals', and clinics', so that those providers can meet patients' legitimate medical needs. Importantly, distributors do not have authority to prevent prescription opioid abuse that may occur after legitimate and lawful prescriptions are dispensed to patients.

23. Based on my work performed in this matter and my industry experience, it is my opinion to a reasonable degree of professional certainty that Walgreens maintained effective controls against diversion in light of its business model and customer base. Using its judgment based on its knowledge of its customers, Walgreens designed and operated a suspicious order monitoring system to identify suspicious orders, i.e., orders of unusual size, deviating from a normal pattern, and of unusual frequency prior to shipment. Further, although not stated as a requirement under the CSA or its implementing regulations, Walgreens also engaged in due diligence and used its knowledge of its customers to ensure that no suspicious orders were shipped and that no shipped orders were diverted to illegitimate channels.

24. There is no evidence that any orders from Walgreens' distribution centers to Cuyahoga and Summit Counties were diverted to illicit channels, much less that they contributed to the opioid epidemic.

25. There are many flaws in Plaintiffs' experts' reports. For example, the flagging methodologies employed by Dr. McCann and endorsed by Mr. Rafalski are arbitrary and unsupported. The analyses presented by Dr. McCann and used by Mr. Rafalski to support his claims of diversion only show volumes of shipments, with no assessment of any individual order or any store-specific factors. Mr. Rafalski's assumption of no or insufficient due diligence renders his entire opinion speculative and unreliable.

IV. Information Relied Upon

26. In conducting my work and forming my opinions in this matter, I have reviewed documents and other information produced by the parties in this matter, publicly available information, conversations with Walgreens personnel, conversations with other experts retained by Walgreens, as well as my skills, knowledge, training, and experience in both an enforcement role with the DEA and an industry compliance role at Amneal. None of my opinions are based on non-public information derived solely from my time at the DEA.

27. I have held conversations with the following individuals:

- John Merritello, Program Manager - Retail Systems/Marketing Systems/Inventory System of Walgreens; and
- Robert Brunner, Vice-President of Charles River and Associates, retained by Walgreens. I have also attached Mr. Brunner's expert report with appendices and supplemental production to my report as **Appendix E**.

28. A listing of documents reviewed, considered, and/or relied upon by me can be found in **Appendix B** attached to this report.

V. Background

A. Plaintiffs

29. The Plaintiffs in this matter (Cuyahoga County and Summit County) are county entities that provide governmental services to their residents including law enforcement, public assistance, and justice services.

30. Cuyahoga County is an Ohio state county based in and around the city of Cleveland. Summit County is an Ohio state county located south of Cuyahoga County and it is based in and around the City of Akron. Cuyahoga and Summit counties are estimated to be the second and fourth most populous counties in Ohio.[6] The cities of Akron and Cleveland are the largest cities in Summit and Cuyahoga County, respectively.

B. Walgreens

31. Walgreen Co. is an American corporation headquartered in Deerfield, Illinois and was founded in 1901.[7] Walgreens operates a large chain of retail and pharmacy stores.[8]

32. Since 2000, the number of Walgreens pharmacy and retail store locations have increased significantly. In August 2000, Walgreens operated 3,162 retail stores;[9] by August 2010, Walgreens had doubled its number of retail stores to 7,562 retail stores;[10] and in August 2018, Walgreens operated 9,560 retail stores.[11] In the distribution timeframe for which data is

[6] https://www.ohio-demographics.com/counties_by_population.
[7] https://www.walgreens.com/topic/about/history/ourpast.jsp; On December 31, 2014 Walgreens completed its acquisition of Alliance Boots GmbH (https://www.chicagotribune.com/business/ct-walgreen-completes-merger-0101-biz-20141231-story html), and Walgreens Boots Alliance became the successor of Walgreen Co. (Walgreens Boots Alliance, Inc. Form 10-K for fiscal year ended August 31, 2018, p. 1.)
[8] Walgreens Boots Alliance, Inc. Form 10-K for fiscal year ended August 31, 2018, p. 1.
[9] Walgreen Co. Form 10-K for fiscal year ended August 31, 2000, p. 1.
[10] Walgreen Co. Form 10-K for fiscal year ended August 31, 2012, p. 1.
[11] Walgreens Boots Alliance, Inc. Form 10-K for fiscal year ended August 31, 2018, p. 3.

available, i.e., 2002 to 2014, Walgreens operated 59 pharmacies in Cuyahoga and Summit Counties.[12]

33. Walgreens reports that stores that are located in freestanding locations are more convenient for customers, enable drive-through pick-up windows, and offer greater visibility in intersections as compared to stores that are located in strip-malls or in other non-freestanding locations.[13] Walgreens has relocated existing stores to freestanding stores over time. For example, Walgreens added 212 store locations in fiscal year 2012, of which 169 were new or relocated drugstores.[14]

34. Walgreens' distribution centers ("Walgreens Distribution Centers") currently supply only non-pharmaceutical products to the retail stores. Walgreens gradually ceased distributing all controlled substances to its retail stores starting in at least March 2013 with full transition to a third-party distributor in 2014.[15] When Walgreens Distribution Centers were distributing controlled substances, Walgreens Distribution Centers supplied only Walgreens retail stores; i.e., not third-party pharmacies, hospitals, clinics, etc.[16] Walgreens Distribution Centers traditionally acquired controlled substances directly from manufacturers, and then Walgreens Distribution Centers supplied the pharmaceuticals to its retail pharmacies.[17] In the distribution timeframe of interest in this matter, i.e., 2002 through 2014, Walgreens Distribution Centers shipped controlled substances into Cuyahoga and Summit Counties; three of those distribution centers shipped Schedule II drugs.

[12] Expert Report of Robert L. Brunner, May 10, 2019, p. 12.
[13] Walgreen Co. Form 10-K for fiscal year ended August 31, 2000; August 31, 2004; and August 31, 2012; Conversation with John Merritello.
[14] Walgreens Co. Form 10-K for fiscal year ended August 31, 2012.
[15] Walgreen Co. Form 10-K for fiscal year ended August 31, 2013; Walgreen Boots Alliance, Inc. Form 10-K for fiscal year ended August 31, 2015, p. 5.
[16] Deposition of Edward Bratton, November 30, 2018, p. 38; Deposition of Patricia Daugherty, November 15, 2018, p. 223; Deposition of Wayne Bancroft, January 10, 2019, pp. 90-91; Deposition of Douglas Peterson, December 20, 2018, pp. 47, 53; WAGFLDEA00001746 (Customer Authentication Policy & Procedure); Deposition of Kyle Wright, February 28, 2019, pp. 226, 228, 230.
[17] Walgreen Co. Form 10-K for fiscal year ended August 31, 2013, p. 14.

35. The last shipments of oxycodone by a Walgreens Distribution Center into these counties was March 4, 2013.[18] The last shipments of hydrocodone by a Walgreens Distribution Center into these counties was April 9, 2014 and April 4, 2014, respectively.[19]

VI. Prescription Opioid Abuse Trends Over Time

36. Opioid abuse in this country is not new to this century. As discussed above, my drug enforcement career began in the 1980s, with my first years including efforts to combat heroin abuse within the Detroit metropolitan area. Opium is the key raw material in producing heroin. Prescription opioid drugs use the same raw material base as heroin – opium. My first prescription opioid investigation involved the prescription drug pentazocine (Talwin) and an OTC antihistamine that was blue in color (street name T's and Blues). The prescription drug Talwin was approved by the FDA in 1967.[20] Its original acceptable medical use was to treat pain. Heroin abuse became a high law enforcement priority, so heroin distributers looked for a substitute that satisfied addicts and gave them easier access with less visibility to law enforcement. It was discovered Talwin combined (crushed) with an antihistamine (Blue) creates a synthetic heroin that can be used intravenously. This became the drug of choice in various cities nationwide.[21] In addition to the T's and Blues investigations, other experience with opioid enforcement included undercover operations that identified doctors and pharmacists that were illegally prescribing or dispensing prescription-controlled substances. We cultivated human intelligence and penetrated rogue practitioners or organizations that dispensed or distributed illicit controlled substances. After T's and Blues, a number of other opiates have been the focus of enforcement activities due to their illicit use.[22]

[18] Rafalski Report, p. 132.
[19] Expert Report of Robert L. Brunner, May 10, 2019, p. 56.
[20] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=016194.
[21] National Trends and Deterrent Strategies for Prescription and OTC Drug Abuse, presented by Joseph Rannazzisi to the Michigan Department of Community Health, Office of Drug Control Policy, dated March 27, 2009, p. 5 (https://www.deadiversion.usdoj.gov/pubs/presentations/stermidcpgov09.pdf).
[22] National Trends and Deterrent Strategies for Prescription and OTC Drug Abuse, presented by Joseph Rannazzisi to the Michigan Department of Community Health, Office of Drug Control Policy, dated March 27, 2009, pp. 3-7 (https://www.deadiversion.usdoj.gov/pubs/presentations/stermidcpgov09.pdf).

37. The next opioid trend I experienced during my career was the methadone crisis. Methadone is used for the treatment of opioid (heroin) addiction. It is also a prescription opioid which is highly addictive. Methadone clinics were increasing all over the country. Due to this demand, rogue and illegal practices that diverted legal medicine into illicit channels increased in many urban and suburban areas. This was the blue print to the rogue pain clinic investigations that we saw in later years. The abuse of prescription opioids has changed over time and continues to change over time, from the opioid of choice to the points of access for it.

38. Since 1970, oxycodone and fentanyl have been listed as Schedule II drugs under the CSA. Hydrocodone was initially listed as a Schedule III drug. All of these drugs have been associated with abuse since their introductions, many of which span many decades back:

- Oxycodone: In 1950, Percodan, a combination of oxycodone and aspirin, received FDA approval for the treatment of pain.[23] In 1976, Percocet, a combination of oxycodone and acetaminophen, was approved by the FDA.[24] Oxycontin was approved in 1995. Per the DEA's Office of Diversion Control, "*[o]xycodone abuse has been a continuing problem in the U.S. since the early 1960s.*"[25]

- Fentanyl: In the 1960s, fentanyl was sold as Sublimaze.[26] Per the DEA's Office of Diversion Control, "*[a]buse of fentanyl initially appeared in the mid-1970's.*"[27] The DEA's Office of Diversion Control also reports that, as of October 2018, "*illicitly manufactured fentanyl*" is "*chiefly responsible for the current domestic crisis*."[28]

[23] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=007337.
[24] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=085106.
[25] https://www.deadiversion.usdoj.gov/drug_chem_info/oxycodone/oxycodone.pdf.
[26] https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf.
[27] https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf.
[28] https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf.

- Hydrocodone: Pure hydrocodone was classified as a Schedule II drug. Vicodin was introduced in the U.S. in 1978, with its generic version launch in 1983.[29] Versions of hydrocodone with lesser doses of hydrocodone in combination with other drugs, like Vicodin (a combination of hydrocodone and acetaminophen), were classified as Schedule III drugs.[30] In 2014, hydrocodone was reclassified as a Schedule II controlled substance.[31]

The popularity of a particular opioid noted above as the preferred opioid of abuse has changed over time in response to increased regulation, enforcement actions, and product availability. Consistent with my experience, Mr. Wright testified that the waves of abused opioids shifted from primarily hydrocodone abuse to oxycodone abuse to fentanyl abuse.[32]

39. Not only has abuse of prescription opioids changed over time, but so have the ways that the prescription opioids are prescribed and dispensed. For example, large numbers of internet pharmacies began operating in the 1990s, where some were legitimate sources to have prescription drugs filled by a legitimate doctor, while others were online storefronts that would prescribe and dispense prescriptions, including controlled substances, following a purported "*safe and secure*" online questionnaire to make diagnoses.[33] However, many of these internet pharmacies did not have legitimate doctor/patient relationships.[34] As of 1995, internet pharmacies were "*taking up a great deal of [the DEA's] time*" and were characterized as "*the biggest problem*" facing the DEA by 2005.[35] In September 2005, "*federal drug investigators shut down 4,600 illegal internet pharmacy sites and arrested 18 people who ran them from locations across the*" U.S.[36] In response to the rise of internet pharmacies, the Ryan Haight

[29] http://nymag.com/news/intelligencer/topic/57770/.
[30] http://nymag.com/news/intelligencer/topic/57770/.
[31] https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm.
[32] Deposition of Kyle Wright, February 28, 2019, p. 118.
[33] https://www nytimes.com/2005/10/24/technology/pharmacies-endorse-crackdown-on-fraud html.
[34] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 96.
[35] Deposition of Kyle Wright, February 28, 2019, p. 89
[36] https://www nytimes.com/2005/10/24/technology/pharmacies-endorse-crackdown-on-fraud html. Specific diversion operations focused on internet pharmacies included Operation Baywatch, Operation Lightning Strike,

Online Pharmacy Consumer Protection Act was passed in 2008.[37] Of the DEA diversion investigations between 2005 and 2009 that were initiated against rogue internet pharmacies, most, if not all, of the domestic-based internet pharmacies were independently-owned pharmacies.[38]

40. In addition to internet pharmacies, pain management clinics or pain clinics started popping up in the early 2000s, especially in Florida.[39] After the decline of internet pharmacies and the passing of the Ryan Haight Act, more DEA resources were devoted to rogue pain clinics.[40] These rogue pain clinics both prescribed and dispensed prescriptions, including controlled substances, inappropriately.[41] In 2008, the DEA estimated that pain clinics in South Florida increased from 60 to 150, with a significant level of concentration of such clinics in Broward County.[42]

41. In my experience with the DEA from 1984 through 2012, generally, more of the agency's focus and other resources were devoted to investigations of high impact and visibility.[43] Typically, these investigations involved heroin, cocaine, crack cocaine, methamphetamine, marijuana, and designer drugs such as ecstasy, GHB and others.[44] In these large, complex investigations, the DEA sought to identify the command structure of organizations and supporting co-conspirators who facilitated illegal drug trafficking, from manufacturers to

---

Operation CyberRX, Operation Cyber Chase (Deposition of Joseph Rannazzisi, April 26, 2019, Exhibit 9 (Congressional Hearing RE: Rogue Online Pharmacies – May 2007), pp. 54-55).

[37] https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf.

[38] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 219-220.

[39] Rigg, K. et al. "Prescription Drug Abuse & Diversion: The Role of the Pain Clinic." *J Drug issues*. 2010; 40(3): 681-702; Deposition of Joseph Rannazzisi, April 26, 2019, Exhibit 11 at p. 83 (Rannazzisi Statement to Congress – March 2012).

[40] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 200, 221.

[41] Rigg, K. et al. "Prescription Drug Abuse & Diversion: The Role of the Pain Clinic." *J Drug issues*. 2010; 40(3): 681-702.

[42] Rigg, K. et al. "Prescription Drug Abuse & Diversion: The Role of the Pain Clinic." *J Drug issues*. 2010; 40(3): 681-702.

[43] In 2008, the DEA stated that it was "*focus[ing] its resources on fewer, yet more complex trafficking organizations and the financial entities (money launderers, financial institutions, etc.) that support them*" (Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 104).

[44] Many of these drugs are highly abused with large trafficking volume and violence associated with the trade (Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, pp. 11-15).

importers to distributors.[45] These organizations are international cartels, syndicates, and illicit business fronts that engage in international smuggling to national and local open-air trafficking. Characteristics of these organizations were usually associated with violence, weapons, and money laundering.[46] Examples of some of these investigations in the 2000's include the following:

- Operation Panama Express:[47] This was a long-running OCDETF investigation comprising participants from various government agencies. According to March 2006 Congressional testimony, Operation Panama Express targeted the highest-level traffickers responsible for the financing, production, transportation, and distribution of cocaine throughout North America and Europe. Since its inception in February 2000 through 2005, 356 metric tons of cocaine was seized, 109.2 metric tons of cocaine was scuttled, and 1,107 individuals were arrested.

- Operation Black Gold Rush:[48] Also, in 2006, federal agents arrested more than 130 alleged drug traffickers in 15 cities across the U.S. The heroin was smuggled into the U.S. from Mexico, where delivery was through a phone-up home delivery shop like a take-out pizza shop.

- In March 2006, the International Narco-Terrorism Provisions in the USA Patriot Improvement and Reauthorization Act of 2005 enhanced DEA's investigative authority overseas.[49] The law gave the DEA the authority to investigate international criminal organizations that use illicit drug proceeds to promote and finance foreign terrorist organizations and acts of terror. With this amended law,

[45] DEA Congressional Budget Submission for Fiscal Year 2017, pp. 1, 55.
[46] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2009, pp. 11-12; Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2010, p. 5; Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 17.
[47] https://web.archive.org/web/20060615060708/http://www.dea.gov/pubs/cngrtest/ct033006 html.
[48] https://www.chicagotribune.com/news/ct-xpm-2006-08-16-0608160333-story.html.
[49] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2010, pp. 34-35.

> DEA's role in narco-terrorism investigations and prosecutions expanded significantly.

42. Throughout the 2000s, these examples were the types of investigations DEA targeted as priorities.[50] Consistent with my experience, in 2008, the DEA stated that the number of open diversion investigations was "*decreasing as DEA focuses its resources on fewer, yet more complex trafficking organizations, and the financial entities (money launderers, financial institutions, etc.) that support them*."[51] For example, between 2006 and 2015, the ARCOS group at DEA headquarters did not provide pro-active, quarterly threat assessments to the field divisions at DEA.[52]

43. In summary, abuse of prescription opioids has been present in the U.S. for decades, with the preferred prescription opioid of abuse changing over time in the last 30 years from hydrocodone to oxycodone to fentanyl. In addition to different opioids, outlets such as internet pharmacies, pain clinics, and pill mills became popular avenues for patients to illegitimately access prescription opioids. As can be gleaned from publicly available information, from at least the "war on drugs" by President Nixon in the 1970's until the time I retired from the DEA, DEA enforcement operations were less focused on prescription opioids as compared to traditional illegal drugs given the more serious implications of these other drug challenges.

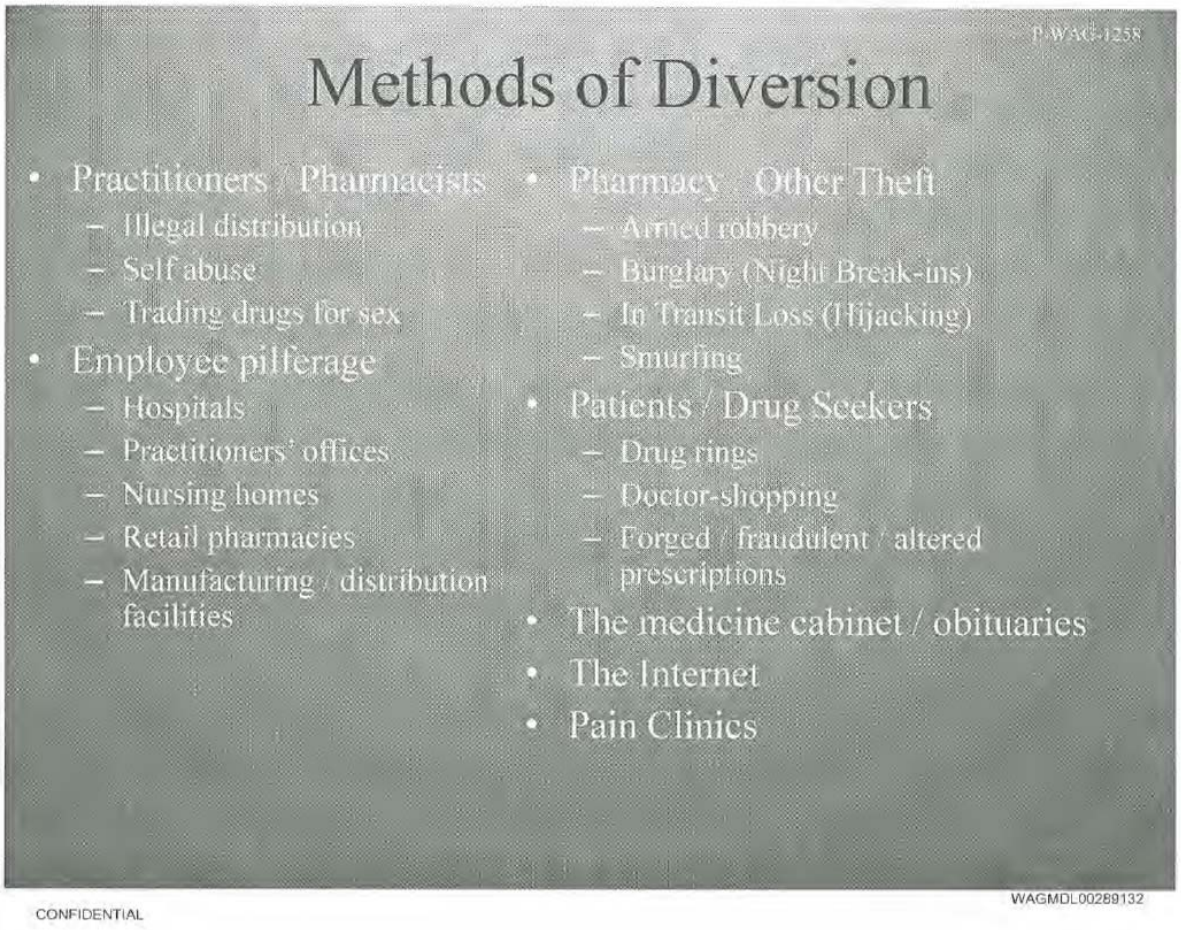
VII. Diversion of Controlled Substances

44. The intent of the CSA was to create a "closed system" for controlled substances, where all parties involved in the prescribing, manufacturing, distributing, and dispensing of controlled substances are qualified and registered with the DEA to handle such substances. DEA-registered participants in the closed system include practitioners, manufacturers, distributors, and pharmacies, hospitals, and clinics. DEA-registered manufacturers make

[50] See also https://www.dea.gov/sites/default/files/2018-07/1999-2003%20p%2091-118.pdf; https://www.dea.gov/sites/default/files/2018-07/2003-2008%20p%20118-153.pdf; https://www.dea.gov/sites/default/files/2018-07/2009-2013%20p%20153-179.pdf.
[51] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 104.
[52] Deposition of Thomas Prevoznik, April 18, 2019, p. 508. Since DEA leadership change in 2015, ARCOS data is now used for threat assessments again (Deposition of Thomas Prevoznik, April 18, 2019, p. 509).

prescription opioids that are prescribed for patients by DEA-registered practitioners. DEA-registered distributors provide inventory of the manufacturers' prescription opioids to DEA-registered pharmacies. DEA-registered pharmacists dispense the controlled substances to patients.

45. Diversion can loosely be defined as the redirection of narcotic drugs and psychotropic substances from the legitimate distribution chain of medical and scientific use into illicit channels. When a controlled substance is taken out of this closed system for illicit use, it is "diverted". There are many methods of diversion, as shown in a presentation that Mr. Rannazzisi gave in 2012:[53]



[53] Deposition of Edward Bratton, November 30, 2018, Exhibit 5 at WAGMDL00289132 (Drug Trends Presentation – December 2012).

Diversion can involve practitioners' behaviors (self-abuse or selling), employees pilfering at various outlets with controlled substances, robberies and burglaries of pharmacies or other outlets, patients and drug seekers finding illegitimate/illegal supply sources, stealing from legitimate patients' medicine cabinets, and illegitimate internet pharmacies and pain clinics. Many of these diversion methods would be outside the purview of distributors and pharmacies in the closed system for controlled substances.

46. Distributors are a bridge between manufacturers and retailers. A distributor is in charge of the portion of the controlled substance supply chain that connects the manufacturers to the pharmacies, hospitals, or clinics that legitimately and legally dispense medications to patients that have legitimate and legal prescriptions. Their job is to efficiently, safely, and securely make sure that the medication legitimately prescribed by a practitioner is available at the pharmacy. Distributors have anti-diversion controls to limit theft or loss of pharmaceuticals from the manufacturer to its distribution centers, and then from its distribution centers to the retail pharmacies. Anti-diversion controls are in place for receiving prescription opioids at distribution centers (from DEA registered manufacturers), reporting movements and inventory, working in controlled substance vaults and cages at distribution centers, fulfilling orders at distribution centers, storing controlled substances, and securely transporting controlled substances to pharmacies (that are DEA registered).

47. Diversion also includes patients or drug-seekers stealing legitimately-prescribed opioids from family members' medicine cabinets or illegally selling prescription opioids that were obtained through legitimate channels.[54] Once a patient fills a legitimate and legal prescription, the controlled substance is now outside the closed system. Should a patient elect to give or sell his legitimately and lawfully obtained prescription opioids to others, that is outside the purview of the closed system and becomes the responsibility of law enforcement.

48. In summary, a distributor's role in the pharmaceutical supply chain is to facilitate pharmaceuticals from the manufacturer to pharmacies, hospitals, or clinics. As discussed in

[54] Deposition of Joseph Rannazzisi, April 26, 2019, p. 53.

greater detail in Section IX.A, Walgreens Distribution Centers only distributed to its own retail pharmacies. As such, many of the diversion methods identified by the DEA in the slide above would not have been relevant to Walgreens Distribution Centers; e.g., internet pharmacies, pain clinics, thefts from medicine cabinets and patients, etc. As a self-distributor, Walgreens Distribution Centers' anti-diversion controls kept controlled substances out of illegitimate channels, where these illegitimate channels included internet pharmacies and theft by employees or other persons involved in the security and transportation of controlled substances within the distribution arm. I have seen no evidence that Walgreens ever shipped to an illegitimate channel. Finally, distributors and self-distributors like Walgreens were not law enforcement officers with the authority to police downstream illegal sales of prescriptions derived from proper, lawful prescriptions.

VIII. Regulation of Controlled Substances

A. The Controlled Substances Act

49. Drugs and other substances that are considered controlled substances under the Controlled Substances Act ("CSA") are divided into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.[55] Schedule II Controlled Substances "*have a high potential for abuse which may lead to severe psychological or physical dependence.*"[56] Schedule III Controlled Substances "*have a potential for abuse less than*" Schedule II drugs and "*abuse may lead to moderate or low physical dependence or high psychological dependence.*"[57] Hydrocodone was a Schedule III drug until October 2014.

50. While serving as Vice-President of DEA Compliance/Corporate Security at Amneal, I looked to the CSA and 21 CFR § 1301.74 for guidance in handling Schedule I through V controlled substances. Per the CSA established in 1971, manufacturers, distributors, and dispensers of controlled substances need to be registered with the DEA to handle controlled

[55] https://www.deadiversion.usdoj.gov/schedules/index.html.
[56] https://www.deadiversion.usdoj.gov/schedules/index.html.
[57] https://www.deadiversion.usdoj.gov/schedules/index.html.

substances. After applying, distributors are registered "*to distribute a controlled substance in schedule[s II - V] unless [the Attorney General] determines that the issuance of such registration is inconsistent with public interest.*"[58] Public interest considerations by the Attorney General include the following:[59]

a) *"maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;*

b) *compliance with applicable State and local law;*

c) *prior drug-related conviction record of applicant under Federal or States laws relating to the manufacture, distribution, or dispensing of such substances;*

d) *past experience in the distribution of controlled substances; and*

e) *such other factors as may be relevant to and consistent with the public health and safety."*

51. Upon satisfaction of the above factors, the DEA will register the applicant. DEA registration serves as "*the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations.*"[60] DEA registration is also the "*primary means*" by which manufacturers, distributors, and practitioners are "*given legal authority to handle controlled substances*."[61]

[58] 21 USC § 823(b)(1) and (e)(1).
[59] 21 USC § 823(b)(1) and (e)(1).
[60] ABDCMDL00269691 – 694 (September 2006 Rannazzisi Letter).
[61] ABDCMDL00269691 – 694 (September 2006 Rannazzisi Letter).

B. DEA Regulations, § 1301.74(a) – (e)

52. Manufacturers, distributors, dispensers, and prescribers that receive registrations for distributing and handling controlled substances also consult the Code of Federal Regulations. Per 21 CFR § 1301.74(a) – (e):[62]

a) *"Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a* ***good faith inquiry*** *wither with the [DEA] or with the appropriate State controlled substances registration agency, if any,* ***to determine if that person is registered*** *to possess the controlled substance.*

b) *The registrant shall* ***design and operate a system to disclose*** *to the registrant* ***suspicious orders*** *of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.* ***Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency****.*

c) *The registrant must notify the Field Division Office of the Administration…, in writing, of any* ***theft or significant loss*** *of any controlled substance within one business day of discovery of the theft or loss…The registrant must also complete, and submit to the Field Division office in his or her area, DEA Form 106 regarding the theft or loss.*

d) *The registrant shall not distribute any controlled substance listed in Schedules II through IV as a complimentary sample to any potential or current customer…;*

[62] 21 CFR § 1301.74(a) – (e) (emphases added). There are other components (f) through (m) that I have not listed here.

> *e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements sent for in 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses."*

53. In addition, non-practitioners such as distributors are subject to regulations regarding the physical security controls for handling controlled substances as discussed in 21 CFR § 1301.72(1).[63] Depending on the controlled substance, physical security requirements include vault, cage, safes and building construction specifications, access control, alarm and other surveillance equipment, self-closing and -locking mechanisms, as well as others.

54. DEA registrants are required to pay registration fees on an annual or multi-year basis, depending on the type of registrant.[64] The table below summarizes the registrant fees collected by the DEA into the Diversion Control Fee Account from fiscal year 2008 and projected through fiscal year 2020:[65]

[63] https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm.
[64] https://www.deadiversion.usdoj.gov/drugreg/categories htm.
[65] Receipt Collections from DEA 2020 Congressional Budget Submission, Exhibit N. For 2008, Receipt Collections is calculated as "Net Receipt Collections" plus $15 million of receipt collections "Retained in the General Treasury". (https://www.justice.gov/file/1144616/download)

DEA Diversion Control Fee Account
Receipt Collections by Year

Year		Receipt Collections
2008	$	235,904,000
2009		249,512,000
2010		245,836,000
2011		257,674,000
2012		309,223,000
2013		359,326,000
2014		372,876,000
2015		388,765,000
2016		397,085,000
2017		416,418,000
2018		425,749,000
Total (Actual)	**$**	**3,658,368,000**
2019 Projected		443,813,000
2020 Projected		460,911,000
Total (2008-2020 Projected)	**$**	**4,563,092,000**

55. Customers that order controlled substances from distributors will submit a Form 222 or submit electronic orders through the DEA's Controlled Substance Ordering System ("CSOS").[66] Also, manufacturers and distributors are required to track and record changes in inventory to account for the location of each dosage unit, whether it is an inter-agency transfer, sale, destruction, or return, and have such records "*readily retrievable*" upon request. To the extent any controlled substances are subject to theft or loss in transit, the manufacturer or distributor must file a Form 106 with the DEA.[67] To the extent any controlled substance is deemed quarantined (i.e., expiration damaged, or not suitable for consumption) for destruction, the manufacturer or distributor would file Form 41 with the DEA.

56. Data provided by manufacturers and distributors from Form 222 (or CSOS) and Form 106 are compiled across all manufacturers and distributors into the DEA's Automation of Reports and Consolidated Orders System ("ARCOS").[68] "*ARCOS is an automated,*

[66] https://www.deaecom.gov/.
[67] https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.
[68] https://www.deadiversion.usdoj.gov/arcos/handbook/section1 htm.

comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions."[69] Manufacturers and distributors are required to "*periodically report to DEA (ARCOS) their inventories of selected controlled substances and increases and decreases to the inventories of these substances*", as mandated by 21 CFR § 1304.[70]

57. "*ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.*"[71] The DEA uses the ARCOS data to create "*reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts.*"[72] ARCOS data provides the DEA and other enforcement agencies with detailed information on the types of controlled substances, quantities, flow, and entity dispensing to consumers. Manufacturers and distributors have historically not had access to the full ARCOS data, unlike the government agencies.[73]

58. The DEA's Office of Diversion Control is charged with "*achiev[ing] the mandates of the CSA*" and has "*responsibility for all activities related to the regulation and enforcement of controlled substances and chemicals.*"[74] Diversion Control's "*goal is to prevent, detect, and eliminate the diversion of pharmaceutical controlled substances and chemicals into the illicit market while ensuring adequate supplies are available to meet legitimate medical, scientific,*

[69] https://www.deadiversion.usdoj.gov/arcos/index html#background.
[70] https://www.deadiversion.usdoj.gov/arcos/handbook/section1 htm.
[71] https://www.deadiversion.usdoj.gov/arcos/handbook/section1 htm.
[72] https://www.deadiversion.usdoj.gov/arcos/index html#background; Deposition of Thomas Prevoznik, April 18, 2019, p. 504.
[73] Deposition of Joseph Rannazzisi, April 26, 2019, p. 25.
[74] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 95.

industrial, and export needs."[75] The DEA has never taken the position that legitimate prescriptions for controlled substances should not be filled by pharmacists; rather, the DEA's focus is keeping pharmaceutical controlled substances out of illicit markets.[76]

59. From my review of publicly available information and the record in this case, it is clear that the DEA's expectations regarding compliance with 21 CFR § 1301.74(b) changed over time, and that DEA's guidance around meeting those changed expectations was nominal. DEA provided little substantive guidance or communication to manufacturers and distributors on DEA's expectations. This created uncertainty and confusion among industry participants regarding what was expected and what would be found acceptable by DEA.

C. Methods for Identifying Excessive or Potentially Suspicious Orders

60. DEA approved distributors' proposed programs for identifying excessive or potentially suspicious orders for decades, using formulas based on a multiple of an average. In 1998, the Suspicious Orders Task Force published a report on methods of identifying excessive or potentially suspicious orders of listed chemicals that was explicitly based on similar methods that had already been approved for controlled substances.[77] In January 2004, the DEA published a version of its Chemical Handler's Manual[78] containing the same formula for identifying excessive or potentially suspicious orders that appears in the Suspicious Orders Task Force Report.[79] Appendix E-3 applies to List 1 Chemicals as well as Schedule II-V controlled substances and was noted for use in "*Automated Tracking Systems*," where a computer may be

[75] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 95.
[76] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2008, p. 95.
[77] Deposition of Seth Whitelaw, May 16, 2019, Exhibit 5 at p. 22 (Suspicious Orders Task Force Report) (task force recommending that wholesale distributors who are able to do so "*use the DEA-approved Suspicious Order Monitoring System in use by wholesale drug distributors for controlled substances as enhanced by the Task Force in Appendix A, Exhibit 2*").
[78] Deposition of Edward Bratton, December 16, 2018, Exhibit 6 (Chemical Handler's Manual).
[79] Deposition of Seth Whitelaw, May 16, 2019, Exhibit 5 at Appendix A: 4 [pdf page 41] (Suspicious Orders Task Force Report); CAH_MDL_PRIORPROD_HOUSE_0002207 – 298 at CAH_MDL_PRIORPROD_HOUSE_0002247 (1998 Task Force Report).

needed "*to manage and report on high volume transactions.*"[80] The formula is discussed within Appendix E-3.[81]

U.S. Department of Justice
Drug Enforcement Administration

Chemical Handler's Manual
January 2004

Appendix E-3

Suspicious Order Reporting System for Use in Automated Tracking Systems

Terms & Definitions

This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious and therefore require reporting to DEA.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)

3) Divide total quantity purchases by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

[80] Deposition of Edward Bratton, December 16, 2018, Exhibit 6 at WAGMDL00396010 (Chemical Handler's Manual).
[81] Deposition of Edward Bratton, December 16, 2018, Exhibit 6 at WAGMDL00396010 (Chemical Handler's Manual).

The formula provided Distribution Centers with an instruction on calculating:

- purchase quantities over the last twelve months,
- "*for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other),*"
- and dividing by the total non-zero months within the last twelve months.

Then, the resulting value would be multiplied by a factor of 3. At the end of each month, any orders that exceeded the monthly calculated amount would be reported to DEA, after the purchases were completed.[82]

61. The Chemical Handler's Manual noted that "*when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions.*"[83] Absent a reason to suspect that an order is intended for illicit purposes or an illegitimate channel, the manual provides no guidance that due diligence or investigation is necessary. In addition, the manual states that only registrants who "*fail[] to implement a system to prevent diversion"* may be subject to penalties.[84]

62. The monthly reports based on the Appendix E-3 formula were often referred to as "Excessive Purchase Reports."[85] The Excessive Purchase Reports were often paper print-outs from a computer that listed controlled substance orders that the distributor or registrant had identified as excessive, whether defined by the registrant's own criteria or defined by the formula

[82] Deposition of Edward Bratton, December 16, 2018, Exhibit 6 at WAGMDL00396010 (Chemical Handler's Manual).
[83] Deposition of Edward Bratton, December 16, 2018, Exhibit 6 at WAGMDL00395988 (Chemical Handler's Manual).
[84] Deposition of Edward Bratton, December 16, 2018, Exhibit 6 at WAGMDL00395988 (Chemical Handler's Manual).
[85] The Rafalski Report refers to Excessive Purchase Reports as "Rigid Formula Reports" (Rafalski Report, pp. 119-120). These reports were also referred to as Suspicious Control Drug Order reports (Walgreens) and Ingredient Limit Reports (Cardinal).

in Appendix E-3.[86] Indeed, the Excessive Purchase Reports submitted by distributors could be based on thresholds set by the distributors.[87]

63. The use of Excessive Purchase Reports was in place for decades and was "*blessed by various DEA offices*."[88] DEA understood that distributors submitted the Excessive Purchase Reports "*in order to meet their…suspicious order reporting obligations under 1301.74*."[89]

64. Not only was the use of Appendix E-3 widely used in the industry to identify excessive orders, but many industry participants submitted reports for Schedule II controlled substances that had already shipped. DEA understood that it was "*standard practice in the industry to submit Excessive Purchase Reports while continuing to ship product*."[90] Ms. Ashley confirmed that in her experience, Excessive Purchase Reports typically reflected orders that had been shipped.[91]

65. In summary, it is my opinion based on my review of publicly available DEA guidance, as well as documents and testimony from DEA witnesses, that over an extended period of time DEA approved of distributors' use of "excessive purchase reports" to meet their obligations under § 1301.74(b).

D. Internet Distributor Initiative: 2005

66. In 2005, Joe Rannazzisi was appointed Deputy Assistant Administrator of the DEA's Office of Diversion Control.[92] The DEA started programs for distributors to focus on monitoring of orders of controlled substances by internet pharmacies with potential illicit or unlawful

[86] Deposition of Kyle Wright, February 28, 2019, p. 70.
[87] Deposition of Kyle Wright, February 28, 2019, p. 70.
[88] Deposition of Kyle Wright, February 28, 2019, pp. 70, 72; *see also* US_DEA-00025683 (December 27, 1988 Buzzeo Letter to Walgreens).
[89] Deposition of Demetra Ashley, March 15, 2019, p. 30.
[90] Deposition of Kyle Wright, February 28, 2019, p. 72.
[91] Deposition of Demetra Ashley, March 15, 2019, pp. 28-30.
[92] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 19, 133.

intent.[93] The DEA started the Internet Distributor Initiative to raise "*the awareness of DEA registrants regarding their obligations and possible role in the illegal distribution of pharmaceuticals via the Internet.*"[94] After the DEA added the focus of the Internet Distributor Initiative to include pain clinics, it changed the name to Distributor Initiative Program:[95]

> Additionally, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes.

67. The DEA initiated briefings with each of the three largest wholesale distributors starting in August 2005.[96] The DEA cited success from these first meetings with distributors: "*Based on these meetings, the distributors voluntarily reviewed their customer base and apprised DEA of the termination of business with over 100 known or suspected illegitimate Internet drug trafficking organizations.*"[97] DEA witnesses indicate that Distributor Initiative presentations have continued through at least 2015, though no distributor briefing was ever provided to Walgreens.[98]

68. In addition to Internet Distributor Initiative briefings to communicate with DEA registrants, Mr. Rannazzisi sent letters to manufacturers and distributors with DEA registrations. These letters were a significant departure from past DEA practice under the CSA and §

[93] Deposition of Joseph Rannazzisi, April 26, 2019, Exhibit 8 at pp. 71-72 (Rannazzisi Statement Congress – April 2014).
[94] https://www.govinfo.gov/content/pkg/CHRG-109hhrg25958/html/CHRG-109hhrg25958.htm.
[95] Deposition of Joseph Rannazzisi, April 26, 2019, Exhibit 8 at p. 71 (Rannazzisi Statement Congress – April 2014); Deposition of Thomas Prevoznik, April 18, 2019, p. 471.
[96] Deposition of Kyle Wright, February 28, 2019, p. 91 and Exhibits 10, 11, and 12 (2005 DEA presentations to AmerisourceBergen, McKesson, and Cardinal, respectively); Deposition of Thomas Prevoznik, April 18, 2019, p. 470.
[97] https://www.govinfo.gov/content/pkg/CHRG-109hhrg25958/html/CHRG-109hhrg25958.htm.
[98] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 180, 247-248. Deposition of Kyle Wright, February 28, 2019, pp. 243-244.

1301.74(b). In September 2006, Mr. Rannazzisi sent a letter to "*every commercial entity in the United States registered with the Drug Enforcement Administration to distribute controlled substances.*"[99] The September 2006 letter reminded distributors of their obligations to follow 1301.74(b) by reporting suspicious orders of controlled substances that were identified through a suspicious order monitoring system, where "*suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*"[100]

69. The September 2006 letter also encouraged distributors to "*know your customers*" and initiate policies for better detecting shipments that might be destined for illegitimate channels. To this end, the September 2006 letter contained a series of ten questions to ask a pharmacy when trying to determine whether a suspicious order is indicative of diversion:[101]

> A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:
>
> 1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
> 2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
> 3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
> 4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
> 5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
> 6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
> 7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
> 8. Does the pharmacy offer to sell controlled substances without a prescription?
> 9. Does the pharmacy charge reasonable prices for controlled substances?
> 10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?
>
> These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

[99] ABDCMDL00269691 – 694 at ABDCMDL00269691 (September 2006 Rannazzisi Letter).
[100] ABDCMDL00269691 – 694 at ABDCMDL00269691 (September 2006 Rannazzisi Letter).
[101] ABDCMDL00269691 – 694 at ABDCMDL00269691 (September 2006 Rannazzisi Letter).

70. None of these questions appear in the CSA or the DEA's regulations. Nor does the letter's suggestion that distributors need to "know their customers."

71. In February 2007, Mr. Rannazzisi sent another letter to distributors, using the same language of the September 2006 letter.[102] Mr. Rannazzisi testified that he recalled it was sent again "*to ensure that everyone received the letter.*"[103] Again, suspicious orders were noted as *"orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*"[104]

72. In December 2007, Mr. Rannazzisi sent another letter to manufacturers and distributors of controlled substances. Mr. Rannazzisi testified that the purpose of the December 2007 letter was to reinforce the previous letters and make note of the Southwood Pharmaceuticals decision from 2007.[105]

73. The December 2007 letter departed from DEA's practice of approving suspicious order monitoring systems. It stated:[106]

> Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The December 2007 letter also included specific reference to excessive purchase reports. The letter stated that reliance "*on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders*" and that "[*d*]*aily, weekly, or monthly reports submitted by a registrant indicating 'excessive purchases' do not comply with the requirement to report*

[102] ABDCMDL00269687 – 690 at ABDCMDL00269687 (Feb 7, 2007 letter from Mr. Rannazzisi).
[103] Deposition of Joseph Rannazzisi, April 26, 2019, p. 243.
[104] Deposition of Deborah Bish, February 1, 2019, Exhibit 17 (Dec 27, 2007 letter from Mr. Rannazzisi).
[105] Deposition of Joseph Rannazzisi, April 26, 2019, p. 250.
[106] Deposition of Deborah Bish, February 1, 2019, Exhibit 17 (Dec 27, 2007 letter from Mr. Rannazzisi).

suspicious orders."[107] This represents a significant departure from DEA's past practice of approving the use of excessive purchase reports to meet the regulatory requirements.

74. Finally, Mr. Rannazzisi's December 2007 letter referred readers "*to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc. 72 FR 36487 (2007).*"[108] The Southwood Pharmaceuticals Inc. ("Southwood") matter related to sales of hydrocodone by Southwood to ***internet pharmacies,*** where those internet pharmacies were ***dispensing hydrocodone without legitimate doctor-patient relationships***.[109] At the end of the day, the DEA asserted that Southwood had received information that its customers were illegal internet pharmacies, but nonetheless continued shipping to those internet pharmacies in many instances.[110] As a result, DEA revoked Southwood's DEA registration.[111]

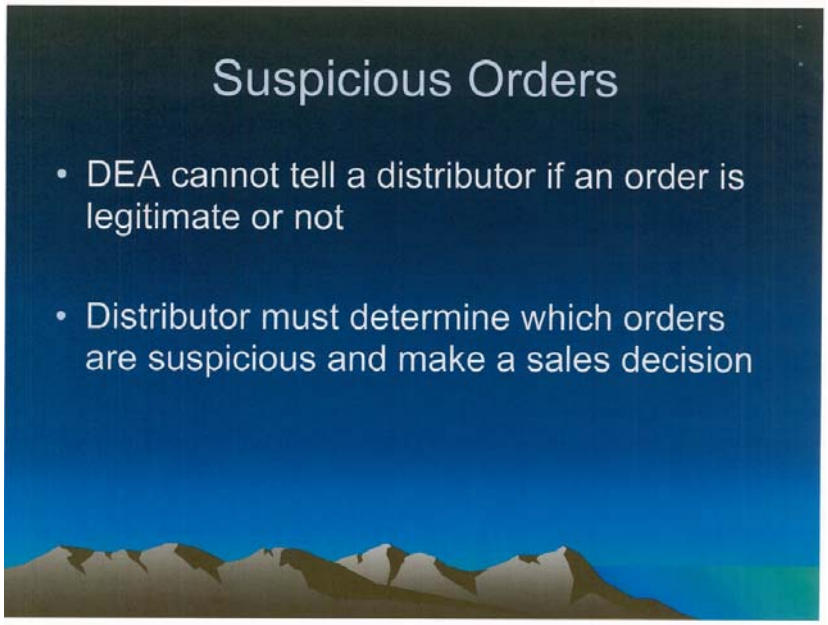
75. In furtherance of its "*Know Your Customer*" initiative for distributors, in April 2011, the DEA prepared "*Suggested Questions a Distributor should ask prior to shipping controlled substances.*"[112] The purpose of the questionnaire was "*to assist the distributor to formulate a better understanding of who their customers are and whether or not they should sell to them controlled substances.*"[113] It was a three-page document with lists of "*possible questions*" for both pharmacies and practitioners to learn more about customers, but "*should not be construed in any manner to be a mechanism or means that you have fully met the criteria and actions required"* by any regulatory bodies.[114] [115]

[107] Deposition of Deborah Bish, February 1, 2019, Exhibit 17 (Dec 27, 2007 letter from Mr. Rannazzisi). As discussed later, the DEA's Drug Diversion website included references to Appendix E-3 through at least March 2013 (see Section VIII.F).
[108] Deposition of Deborah Bish, February 1, 2019, Exhibit 17 (Dec 27, 2007 letter from Mr. Rannazzisi).
[109] https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm.
[110] https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm.
[111] https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm.
[112] Deposition of Edward Bratton, December 16, 2018, Exhibit 11 (Suggested questions document – April 2011).
[113] Deposition of Edward Bratton, December 16, 2018, Exhibit 11 (Suggested questions document – April 2011).
[114] Deposition of Edward Bratton, December 16, 2018, Exhibit 11 (Suggested questions document – April 2011).
[115] When I joined Amneal in 2012, I developed a questionnaire that was completed annually by old and new customers to inquire of any changes in their business activities, any ongoing investigations with law enforcement or regulatory agencies, and other items.

76. In this timeframe, for the first time, DEA stated that its position was to 1) not approve or endorse suspicious order monitoring programs and 2) not identify what a suspicious order was beyond the broad definition in the regulation. This lack of specific guidance and communication with manufacturers and distributors, who are DEA registrants, led to confusion among industry and enforcement participants, as well as delays in implementation.

E. Distributors Determine Which Orders Are Suspicious and Whether to Ship

77. From the very beginning of the first Internet Distributor Initiative presentations in August 2005 to AmerisourceBergen, McKesson, and Cardinal, the DEA indicated that it "*cannot tell a distributor if an order is legitimate or not*":[116]



78. From at least 2005, the DEA took the position that determining if an order was suspicious was a business decision to be made by the distributor because the business had the relevant information:[117]

[116] Deposition of Kyle Wright, February 28, 2019, Exhibits 10, 11 and 12 (2005 DEA Presentations to AmerisourceBergen, McKesson, and Cardinal, respectively).
[117] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 274-275.

> *It depends on the type of due diligence they're [distributors] doing on their customers; whether they know their customers and what their customers' normal ordering patterns are; where is their customer situated; is the customer close to a hospital; is the customer close to – is in a rural area. There's so many dynamics that the drug enforcement administration doesn't have. Only the business, the distributor the registrant has that information.*

Since the business had the information, DEA's policy was not to tell registrants an order is or is not suspicious because, as Mr. Rannazzisi testified, such a determination is:[118]

> *…a business decision that only the – the distributor could make. They're the only ones who know their customers. And they know what their customers are doing. And they know the – the population around the customer's business. They know what is in the area that could warrant an increase or not. So DEA couldn't make that decision. It had to come as a business decision from the distributor.*

79. Ms. Ashley confirmed as well that it is "*within [distributors'] discretion*" to set the criteria that determines if an order deviates from pattern or is too large.[119] Ms. Ashley further testified that there is "*an element of subjectivity*" in 1301.74(b) since the regulation does not provide guidance as to what constitutes an order of unusual size, a deviation substantially from a normal pattern, or unusual frequency.[120] More importantly, Mr. Rannazzisi acknowledged that from 2005 to at least 2015, the DEA did not have internal guidance on what a suspicious order

[118] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 43, 321; see also Deposition of Demetra Ashley, March 15, 2019, pp. 88-89.
[119] Deposition of Demetra Ashley, March 15, 2019, pp. 88-89.
[120] Deposition of Demetra Ashley, March 15, 2019, pp. 26, 146.

was.[121] In the absence of any specific guidance, the DEA advocated it was the business's judgment to determine what constitutes a suspicious order.[122]

80. DEA's Thomas Prevoznik testified similarly, that the DEA understands that SOMs systems are not one-size-fits-all for all registrants in light of their different customers and different business models.[123] And Ms. Ashley agreed that "*[t]here's no direction on how to do*" a monitoring system that would be legally compliant.[124] Mr. Rannazzisi went so far as to say that there did not need to be any guidelines on what made up a successful, compliant suspicious order monitoring system because "*that was the whole idea behind the regulation, to operate, design and operate a system to identify and report suspicious orders*."

81. Furthermore, the DEA provided no guidance on whether and when a registrant can ship an order that it has reported as suspicious or potentially suspicious.[125] As Ms. Ashley explained, the "*DEA was leaving all discretion to the distributor whether or not to ship to a customer. It's their decision.*"[126] Ms. Ashley's testimony is consistent with Mr. Wright's that submission of Excessive Purchase Reports after shipping product did not constitute a violation of DEA rules and regulations.[127] To be sure, neither the CSA nor the regulations say anything about a due diligence requirement. Outside the context where a distributor suspects an order is intended for an illicit channel, DEA's guidance does not call for due diligence either.

82. DEA did not go to Congress to seek any sort of change to the statute or regulations, did not publish any notice of rulemaking, and did not place anything into the Federal Register

[121] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 317-318.
[122] "*[A suspicious order] is a judgment call by the manufacturer based upon their data"* (Deposition of Kyle Wright, February 28, 2019, p. 196).
[123] Deposition of Thomas Prevoznik, April 18, 2019, p. 446.
[124] Deposition of Demetra Ashley, March 15, 2019, pp. 87-88.
[125] Deposition of Demetra Ashley, March 15, 2019, p. 27.
[126] Deposition of Demetra Ashley, March 15, 2019, pp. 194, 241-242.
[127] Deposition of Kyle Wright, February 28, 2019, pp. 115-116.

regarding the changes Mr. Rannazzisi made in his "Dear Registrant" letters and the Internet Distributor briefings.[128]

83. Moreover, at the end of the day, there can be orders that are of unusual size, deviate from normal patterns, and/or be of unusual frequency, but are **not** suspicious orders.[129] Without any internal guidance within the DEA to specify what a suspicious order was or what a suspicious order monitoring system should comprise, DEA personnel were relying on their "*judgment*" to enforce 1301.74(b), much like distributors were expected to rely on their "*judgment*" that their SOM systems were sufficient to comply with non-specific, not communicated, and thus subjective enforcement criteria from the DEA.

84. In my interactions with the DEA while at Amneal, I also experienced a lack of guidance or approval regarding implementation of a suspicious order monitoring system. Although I had been a former DEA employee, my former colleagues would largely no longer engage with me regarding questions or guidance to understand whether or not the suspicious order monitoring protocols that I was implementing into Amneal's controlled substance policy were in compliance with DEA's regulations and requirements. In my experience, the DEA was not open to providing proactive guidance to registrants to get into compliance with the DEA's expectations; rather, the DEA instead put registrants in a reactive position to DEA audits and/or enforcement actions.

85. It is my opinion based on my review of the information produced in this case, as well as publicly available DEA information, that the Rannazzisi letters in 2006 and 2007 reflected a significant change in DEA's expectations regarding how a distributor was to meet its suspicious order monitoring and reporting obligations. Those expectations are not clearly spelled out in DEA guidance, and in fact DEA left it to the distributors themselves to determine what

[128] Deposition of Kyle Wright, February 28, 2019, pp. 126-127.
[129] Deposition of Demetra Ashley, March 15, 2019, pp. 147 – 150; Deposition of Kyle Wright, February 28, 2019, pp. 162-163, 205.

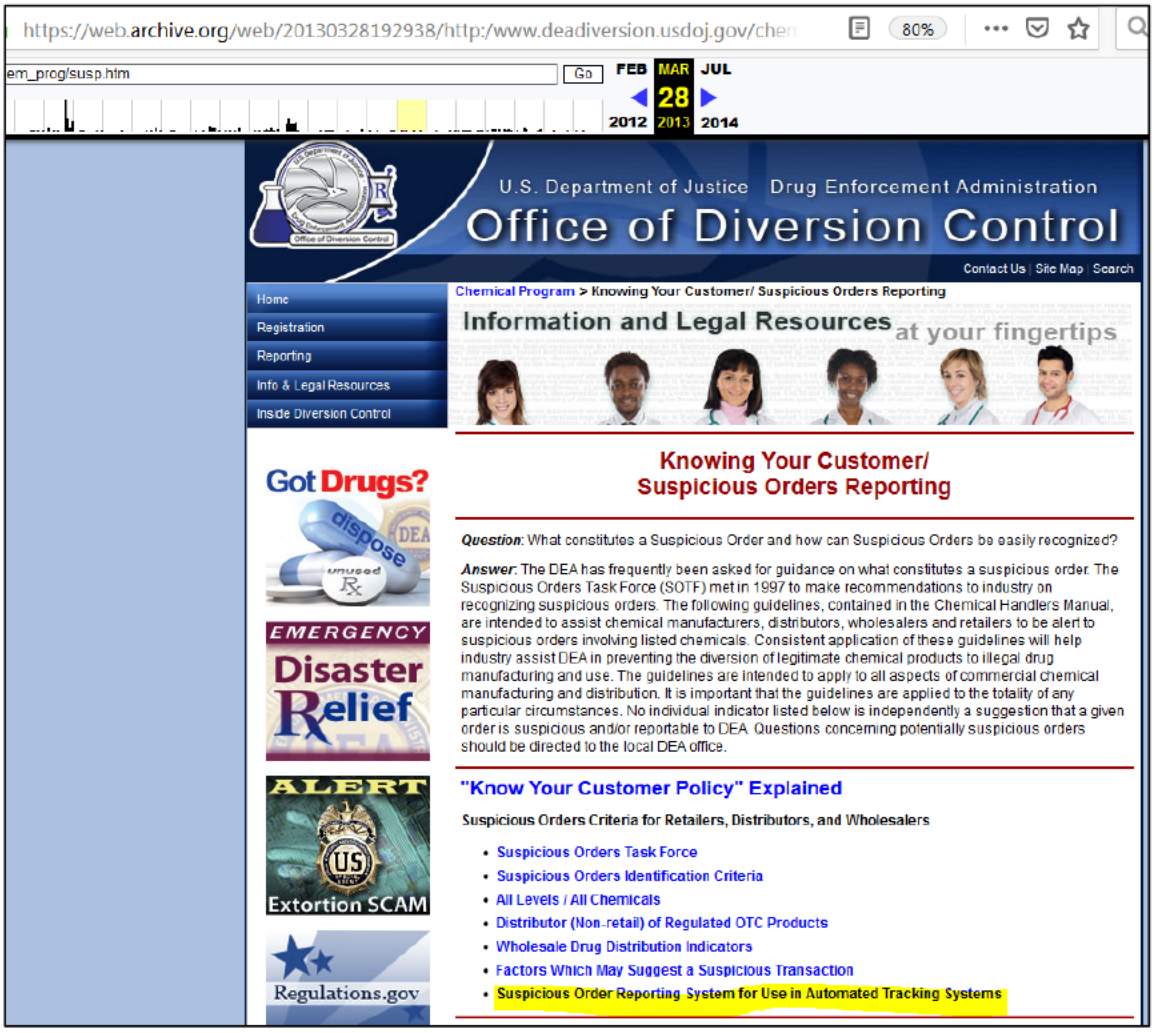
constituted a suspicious order, whether that order was destined for an illicit channel, and whether to report and/or ship that order.

F. Industry Confusion

86. It is no surprise that members of the registrant community were uncertain and confused about how to react to the Rannazzisi letters. Written guidance from DEA is an important tool for registrants seeking to comply with their regulatory commitments, and DEA working with registrants "*helps to ensure compliance*."[130] DEA understood that having written guidance "*creates a reference document for the registrant to use as they work to ensure compliance*."[131] However, industry participants consistently reported that the DEA's lack of guidance combined with a lack of communication and inconsistency across DEA Field Offices created confusion among DEA registrants.

87. Multiple DEA witnesses have confirmed in their testimony in this case that they understood there was "*confusion in the industry*" around DEA's expectations for suspicious order monitoring to the extent that DEA gave conflicting guidance and distributors wanted more clarification.[132] Contributing to industry confusion, the Chemical Handler's Manual Appendix E-3 appeared on the DEA's website as guidance at least as late as March 28, 2013, years after Mr. Rannazzisi's 2007 Dear Registrant letter began discouraging the use of excessive purchase reports.[133] Below is a snapshot of the DEA's "*Knowing Your Customer/Suspicious Orders Reporting*" as archived from March 28, 2013:[134]

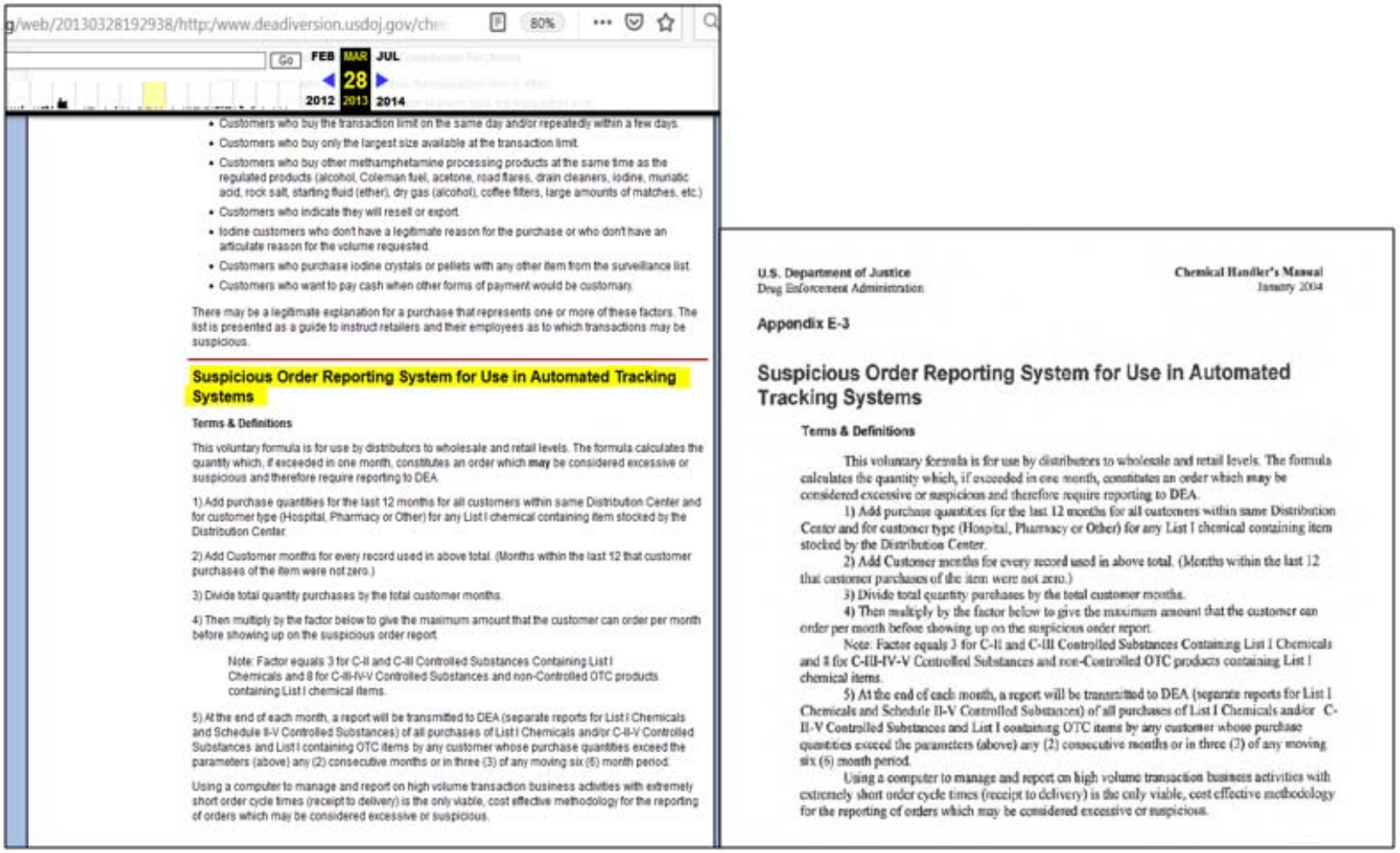
[130] Deposition of Demetra Ashley, March 15, 2019, p. 83.
[131] Deposition of Demetra Ashley, March 15, 2019, p. 84.
[132] Deposition of Kyle Wright, February 28, 2019, p. 120; Deposition of Demetra Ashley, March 15, 2019, pp. 58 – 60, 219.
[133] WAGMDL00400361-364 at WAGMDL00400364 ("Know Your Customer" page on DEA website, March 2013).
[134] https://web.archive.org/web/20130328192938/; http:/www.deadiversion.usdoj.gov/chem_prog/susp.htm.



The yellow-highlighted link titled "*Suspicious Order Reporting System for Use in Automated Tracking Systems*" directed to the following page on the left (see below):[135]

[135] WAGMDL00400361-354 at WAGMDL00400364 ("Know Your Customer" page on DEA website, March 2013).

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division



g/web/20130328192938/http://www.deadiversion.usdoj.gov/ch... 80%

Go FEB MAR JUL
28
2012 2013 2014

- Customers who buy the transaction limit on the same day and/or repeatedly within a few days.
- Customers who buy only the largest size available at the transaction limit.
- Customers who buy other methamphetamine processing products at the same time as the regulated products (alcohol, Coleman fuel, acetone, road flares, drain cleaners, iodine, muriatic acid, rock salt, starting fluid (ether), dry gas (alcohol), coffee filters, large amounts of matches, etc.)
- Customers who indicate they will resell or export.
- Iodine customers who don't have a legitimate reason for the purchase or who don't have an articulate reason for the volume requested.
- Customers who purchase iodine crystals or pellets with any other item from the surveillance list.
- Customers who want to pay cash when other forms of payment would be customary.

There may be a legitimate explanation for a purchase that represents one or more of these factors. The list is presented as a guide to instruct retailers and their employees as to which transactions may be suspicious.

Suspicious Order Reporting System for Use in Automated Tracking Systems

Terms & Definitions

This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which **may** be considered excessive or suspicious and therefore require reporting to DEA.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)

3) Divide total quantity purchases by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

U.S. Department of Justice
Drug Enforcement Administration

Chemical Handler's Manual
January 2004

Appendix E-3

Suspicious Order Reporting System for Use in Automated Tracking Systems

Terms & Definitions

This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious and therefore require reporting to DEA.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)

3) Divide total quantity purchases by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

The formula reported on the DEA's website in March 2013 **matches exactly** the formula in Appendix E-3 of the Chemical Handler's Manual. It was some of the only guidance publicly available to distributors.

88. DEA witnesses who testified in this case knew that the DEA had been criticized for its failure to communicate with the distributor community. Ms. Ashley testified that part of her "*mission*" when she became the Deputy Assistant Administrator at DEA headquarters in 2015 was "*to improve that relationship between the DEA and the distributors*,"[136] thus indicating that the relationship had deteriorated. Ms. Ashley testified that "*important changes*" were made "*within the Office of Diversion Control*," which included accepting meetings in the headquarters office from registrants and directing field offices to increase their engagement with registrants.[137] Ms. Ashley also agreed with comments made by a manufacturer in October 2016 that the DEA was under "*different management*" and had a "*very different philosophy and approach than existed in the recent past*."[138] Mr. Prevoznik agreed that DEA's current leadership has acknowledged that it needs to improve its efforts to collaborate with manufacturers, distributers, and retail chain pharmacies.[139] Mr. Wright testified that lack of approval of systems "*put distributors in a difficult or awkward position*."[140] While at Amneal in a compliance leadership role, I witnessed firsthand the uncertainty of industry participants. From attendance at conferences to telephone calls, there was a lack of knowledge regarding what was sufficient to meet the DEA's expectations, coupled with a lack of communication from DEA officials.

89. A series of meetings and presentations held by the DEA with the National Association of Chain Drug Stores ("NACDS") further demonstrates both that the industry was confused about DEA's expectations regarding suspicious order monitoring, and that DEA was well aware of that fact. In an October 2015 meeting hosted by NACDS featuring Ruth Carter, the new Section Chief of the Office of Diversion Control, notes from the meeting stated, "*The*

[136] Deposition of Demetra Ashley, March 15, 2019, pp. 46-47.
[137] Deposition of Demetra Ashley, March 15, 2019, pp. 49-50.
[138] Deposition of Demetra Ashley, March 15, 2019, p. 56.
[139] Deposition of Thomas Prevoznik, April 18, 2019, p. 466.
[140] Deposition of Kyle Wright, February 28, 2019, p. 132.

biggest takeaway from this Q&A session is that the Office of Diversion Control would like to open dialogue with corporate chain pharmacies among others…In order to promote further progress and leverage current momentum, we will be planning a quarterly engagement with the Office of Diversion Control to facilitate a more open dialogue between the DEA and our members."[141] Consistent with Ms. Ashley's testimony, the DEA was starting to improve its relationship with distributors.

90. In March 2016, NACDS personnel drafted an email identifying "*DEA Meeting Agenda Items*" for an upcoming meeting with the DEA. Below is a snapshot of the requested agenda items:[142]

Requested Agenda Items

- Formal and Informal Guidance from DEA: We would like to discuss a mechanism for formal and informal DEA guidance on regulation compliance and DEA policies such as suspicious order monitoring.
- Collaboration and Communication: We would to discuss better collaboration and better two-way communication, especially at the Field Office level, to prevent and mitigate prescription drug abuse and diversion.
- DEA Field Office Communication: Different DEA Field Offices provide different interpretations of DEA regulations.
- DEA Inspection Process: We would like to discuss DEA inspections of pharmacies.
- Responding to DEA Requests: We have ideas to better facilitate pharmacy responses to DEA requests.
- Prescriber DEA registrations: We have ideas to improve the timeliness and accuracy of DEA prescriber registration information.
- Prescription Drug Disposal Regulations
- Other DEA Regulations: Questions and concerns about existing DEA regulations, including central fill and requirements for a C-II prescription.
- Industry Trends and Insights

KEVIN N. NICHOLSON, R.PH., J.D.
Vice President, Public Policy and Regulatory Affairs
knicholson@nacds.org
P: (703) 837.4183
National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd. Suite 200 Arlington, VA 22209

[141] WAGMDL00442094 – 097 at WAGMDL00442096 (Email RE October 2013 Meeting Notes from NACDS Call with DEA).
[142] WAGMDL00615165 (DEA Meeting Agenda Items Email – March 2016).

91. Not only was formal and informal guidance related to suspicious order monitoring requested, but so was better collaboration and communication at the Field Office level to prevent diversion.[143] Also, just as Mr. Wright testified that confusion existed among DEA agents concerning their inconsistent familiarity with Excessive Purchase Reports,[144] the NACDS asked for greater consistency among Field Offices in interpreting DEA regulations.[145] When asked what the DEA's obligation was when it received a suspicious order, Mr. Wright testified that "*[a] lot of it is up to the discretion of the field office, their manning capability, their workload and all this other kind of stuff. Its priority and its importance, where it ranks.*"[146] I observed such differences across DEA Field Offices that would routinely audit Amneal's facilities in New Jersey, New York, and Kentucky.

92. On April 1, 2016, the NACDS sent an email to its members that stated, among other items, that a "*Meeting with DEA*" would occur on May 3, 2016 at DEA headquarters that included the agenda items noted above.[147] A read-out of the meeting with the DEA on May 3, 2016, included a discussion of the "*long history of inconsistent interpretations and guidance among the various DEA Field Offices*:"[148]

> DEA Field Office Communications: We discussed the long history of inconsistent interpretations and guidance among the various DEA Field Offices. DEA acknowledged this persistent problem, and is increasing their training of DEA Field Office personnel. Moving forward, DEA asks that we attempt to resolve inconsistent communications with the Group Supervisor at the Field Office. If that is not successful in resolving the problem, please report the problem to DEA Headquarters at the following email address: odlp@usdoj.gov.

[143] WAGMDL00615165 (DEA Meeting Agenda Items Email – March 2016).
[144] Deposition of Kyle Wright, February 28, 2019, pp. 120-121.
[145] WAGMDL00615165 (DEA Meeting Agenda Items Email – March 2016).
[146] Deposition of Kyle Wright, February 28, 2019, p. 167.
[147] WAGMDL00615151 – 153 at WAGMDL00615152 (NACDS council email – April 2016).
[148] WAGMDL00502008 – 009 at WAGMDL00502008 (Report of NACDS meeting with DEA – May 2016). Walgreens personnel attended this meeting. (WAGMDL00499183 – 187 (NACDS-DEA meeting notes – August 2017))

Further, despite the DEA indicating that it was going to issue additional guidance on suspicious order monitoring in a February 29, 2016 meeting, the DEA representatives in May 2016 indicated it would be by the end of 2016:[149]

> Suspicious Order Monitoring: At the February 29 meeting, DEA mentioned that the agency WOULD soon issue an NPRM on suspicious order monitoring. On May 3, HOWEVER, DEA stated that they will issue guidance on suspicious order monitoring by the end of 2016. With respect to pharmacies that are seeking guidance in this area, DEA recommended that pharmacies utilize the NABP Red Flags Document.

Although DEA has been considering providing additional information on suspicious order monitoring to registrants since 205, no such definition has been provided to date.[150]

93. Also, over 2015 and 2016, the Government Accountability Office ("GAO") issued reports addressing the DEA's guidance and communications. The GAO provides "*oversight to ensure that government agencies are…focused in performing their duties and their mission.*"[151] In two reports prepared by the GAO in February and June 2015, the GAO made the following recommendations to the DEA related to communicating with DEA registrants and specific to suspicious order monitoring systems:

- "*Identify and implement means of cost-effective, regular communication with distributor, pharmacy, and practitioner registrants, such as through listservs or web-based training*",[152]
- "*Solicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting*", and[153]

[149] WAGMDL00502008 – 009 at WAGMDL00502008 (Report of NACDS meeting with DEA – May 2016).
[150] Deposition of Demetra Ashley, March 15, 2019, p. 70.
[151] Deposition of Demetra Ashley, March 15, 2019, p. 90.
[152] *See* June 2015 GAO Report to Congressional Requesters: Prescription Drugs – More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access ("June 2015 GAO Report"), p. 44.
[153] June 2015 GAO Report, p. 44.

- "*Solicit input from pharmacists, or associations representing pharmacies and pharmacists, about updates and additions needed to existing guidance for pharmacists, and revise or issue guidance accordingly.*"[154]

94. Diana C. Maurer, a Director for the GAO, expanded upon the GAO's recommendations to the DEA in a June 2016 statement made before the Senate Judiciary Committee. In that statement, Ms. Maurer continued to highlight recommendations for greater communication and guidance:[155]

- "*we concluded that although DEA may not be able to provide guidance that will definitively answer the question of what constitutes a suspicious order or offer advice about which customers to ship to, DEA could, for example, provide guidance around best practices in developing suspicious orders monitoring systems*";[156] (emphasis added)

- "*the desire for more or clearer guidance and more communication from DEA was a common theme in the responses offered from both individual pharmacies and chain pharmacy corporate offices to the open-ended questions in our survey related to DEA interactions*";[157] (emphasis added)

- "*DEA raised concerns about the recommendation to solicit input from distributors and stated that short of providing arbitrary thresholds to distributors, it cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers*";[158]

[154] June 2015 GAO Report, p. 44.
[155] Diana C. Maurer expanded on the GAO's recommendations to the DEA in a 2016 statement made before the Senate Judiciary Committee. *See* June 2016 Statement of Diana C. Maurer: Drug Enforcement Administration – Additional Actions Needed to Address Prior GAO Recommendations ("June 2016 Statement"), p. 17.
[156] June 2016 Statement, p. 17.
[157] June 2016 Statement, p. 18.
[158] June 2016 Statement, p. 19.

- "*However, DEA did not mention any plans to develop and distribute additional guidance for distributors. We continue to believe that a guidance document similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their role and responsibilities under the CSA*";[159]

- "*In the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers (i.e., pharmacies and practitioners), which can negatively impact pharmacies and ultimately patients' access;*"[160] and

- "*DEA also commented that it would continue to update or issue guidance as warranted, but again, did not indicate that it had updated, or planned to update, existing guidance to pharmacists related to their roles and responsibilities in preventing abuse and diversion under the CSA.*"[161]

95. Finally, in 2016, the new acting administrator of the DEA, Mr. Chuck Rosenberg, testified to Congress regarding the DEA's relationship with registrants. In his comments, he noted the DEA's shortcomings over the last decade in working with industry: "*We've also been opaque. I think we have been slow. I think we have been opaque. I think we haven't responded to them. We're trying to issue guidelines for them more quickly. We're trying to answer their questions*."[162]

96. In 2016, the Ensuring Patient Access and Effective Drug Enforcement Act became law.[163] It was similar to a bill that passed the House of Representatives in 2015, commonly referred to as the Marino Bill.[164] The law raised the bar to require that shipments pose "*a*

[159] June 2016 Statement, p. 19.
[160] June 2016 Statement, p. 19.
[161] June 2016 Statement, p. 20.
[162] https://www.judiciary.senate.gov/meetings/06/22/2016/oversight-of-the-drug-enforcement-administration (*see* 1:45:28 mark of the hearing video); Deposition of Joseph Rannazzisi, April 26, 2019, p. 61.
[163] https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf.
[164] https://www.congress.gov/bill/114th-congress/house-bill/471.

substantial likelihood of an immediate threat" to be stopped and allowed registrants the opportunity to submit "corrective action" plans, which the DEA would consider before applying any sanctions.[165] Mr. Rannazzisi criticized this law in his deposition testimony,[166] but DEA ultimately withdrew its objections to the bill's passage. By 2016, the number of suspension orders issued by the DEA fell significantly from 2011 levels.[167]

IX. Walgreens' Suspicious Order Monitoring

97. This section will summarize the suspicious order monitoring utilized by Walgreens Distribution Centers over the period Walgreens produced transaction data for oxycodone and hydrocodone distributions (i.e., 2002 through 2014).

A. Walgreens Knew Its Customers

98. When the Internet Distributor Initiative launched in 2005, the DEA focused its efforts on a "*know your customer*" principle because of the growth in internet pharmacies illegitimately dispensing controlled substances.[168] DEA did not launch a corresponding retail chain pharmacy initiative, nor did the DEA deliver similar presentations to retail chain pharmacies (e.g., Walgreens).[169] DEA recognized that chain pharmacies were not rogue pharmacies.[170] DEA exempted retail chain pharmacies (i.e., pharmacies with at least 10 stores) from the enhanced "*know your customer*" due diligence it negotiated with other distributors.[171] Because chain

[165] https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf.
[166] Deposition of Joseph Rannazzisi, May 15, 2019, pp. 401-405.
[167] https://www.washingtonpost.com/investigations/who-is-joe-rannazzisi-the-dea-man-who-fought-the-drug-companies-and-lost/2017/10/15/c3ac4b0e-b02e-11e7-be94-fabb0f1e9ffb_story.html?utm_term=.4ddd873dc510.
[168] Deposition of Kyle Wright, February 28, 2019, Exhibit 11 at MCKMDL00496859 (2005 DEA Presentation to McKesson).
[169] Deposition of Thomas Prevoznik, April 18, 2019, p. 471.
[170] Deposition of Thomas Prevoznik, April 18, 2019, pp. 480-481.
[171] Deposition of Christopher Zimmerman, August 3, 2018, pp. 20, 213-214.

pharmacies were owned by a corporate entity, that information was more easily discernible, and therefore, for chain pharmacies, "*a lot of the information really didn't apply*."[172,173,174]

99. In addition, Walgreens inherently *knew its customers* because Walgreens Distribution Centers distributed solely to their own Walgreens pharmacies. Walgreens never served unaffiliated pharmacies, Internet pharmacies, or pain clinics.[175] At the distributor level, Walgreens had implemented certain policies that effectively addressed the "*know your customer*" principle, namely the Customer Authentication policy and procedure. This policy outlined the process by which distribution centers processed orders from pharmacies. Walgreens did not ship prescription drugs or controlled substances to non-Walgreens entities, and the system, AS/400, did not accept such orders.[176] This policy further required that pharmacies receiving shipments from Walgreens Distribution Centers are authorized to do so. The policy instructs the distribution center that "*Prior to shipping prescription drugs or controlled substances, confirm that each pharmacy has a valid permit from the State Board of Pharmacy and an active registration with the Drug Enforcement Administration.*"[177] Beyond these authentication practices, this policy further addressed shipping to new Walgreens pharmacies such that the distribution center must obtain an understanding of that pharmacy's appropriate inventory needs with respect to projected prescription volume, operating area, and prospective patient population.[178]

[172] Deposition of Christopher Zimmerman, August 3, 2018, pp. 216-217.
[173] Deposition of Christopher Zimmerman, August 3, 2018, p. 268.
[174] Deposition of Kyle Wright, March 4, 2019, Exhibit 36 at HDS_MDL00002036 (Claimant's Request for Production of Documents to Plaintiff – Supplemental Request No. 9); CAH_MDL_PRIORPROD_DEA12_00011059 – 63 at 60 (Pharmaceutical Industry Conference – September 2007).
[175] Deposition of Kyle Wright, February 28, 2019, pp. 226-230; WAGFLDEA00001746 (Customer Authentication Policy & Procedure). Ms. Ashley testified that a distributor that only distributed to its own pharmacies should consider that when identifying suspicious orders or deciding whether or not to ship an order (Deposition of Demetra Ashley, March 15, 2019, p. 248).
[176] WAGFLDEA00001746 (Customer Authentication Policy & Procedure).
[177] WAGFLDEA00001746 (Customer Authentication Policy & Procedure).
[178] WAGFLDEA00001746 (Customer Authentication Policy & Procedure).

100. In 2013, Walgreens developed additional procedures that refer to an individual Walgreens pharmacy as the distribution center's customer. The overview of this procedure is excerpted below:[179]

> **Overview**
> Walgreens Distribution Centers (DCs) *must* take reasonable measures to identify its customers, understand the *normal and expected* transactions conducted by those customers, and identify transactions involving controlled substances that are *suspicious* in nature. For the purpose of this document, a DC "customer" is an individual Walgreen pharmacy. Orders must be assessed to ensure that quantities of controlled substances ordered by a specific location are reasonable. In making these assessments, the DC may consider the pharmacy's clinical business needs, location, and population served. Walgreens ***must report*** to the DEA any order that is determined to be suspicious.

101. Furthermore, Walgreens Distribution Centers know that Walgreens pharmacies have processes and procedures in place to maintain effective controls against diversion. Every retail pharmacy was part of the same organizational hierarchy with accountability at the patient level, pharmacy level, district level, and corporate level. Consistent roles with assigned responsibilities existed across the retail pharmacies with Pharmacy Supervisors, District Managers, District Loss Prevention Managers, and Operations Trainers.[180] Each retail pharmacy was subject to Walgreens' inventory policies, controlled substance reporting policies, vault protocols, Controlled Substance Prescriptions and Good Faith Dispensing policies, and others.[181]

102. It is my opinion based on the documents and testimony produced in this case that Walgreens had a solid understanding of its pharmacies' operations, policies, and procedures, and further, that Walgreens' policies and procedures prevented Walgreens from distributing to any of its pharmacies without first ensuring that the pharmacy was registered with the DEA. Making a

[179] Deposition of Steven Mills, November 8, 2018, Exhibit 12 at WAGMDL00245869 (SOMP Policy and Procedures for Rx Integrity).
[180] WAGMDL00659828 - 856 at WAGMDL00659831 (Walgreens presentation to DEA, July 17, 2012).
[181] WAGMDL00659828 - 856 at WAGMDL00659831, -833 – 840 (Walgreens presentation to DEA, July 17, 2012); e.g., WAGFLDEA00000206 – 207 (Controlled Substance Prescriptions & Good Faith Dispensing Policy, November 8, 2011); WAGFLDEA00005359 (Controlled Substance Prescriptions & Good Faith Dispensing Policy, May 8, 2017); WAGFLDEA00000471 – 475 (Control Substances and Good Faith Dispensing, November 4, 2011); WAGFLDEA00000360 (Targeted Drug Good Faith Dispensing Checklist).

"good faith inquiry" of whether a pharmacy is DEA-registered is the only due diligence requirement explicitly stated in the DEA's regulations.

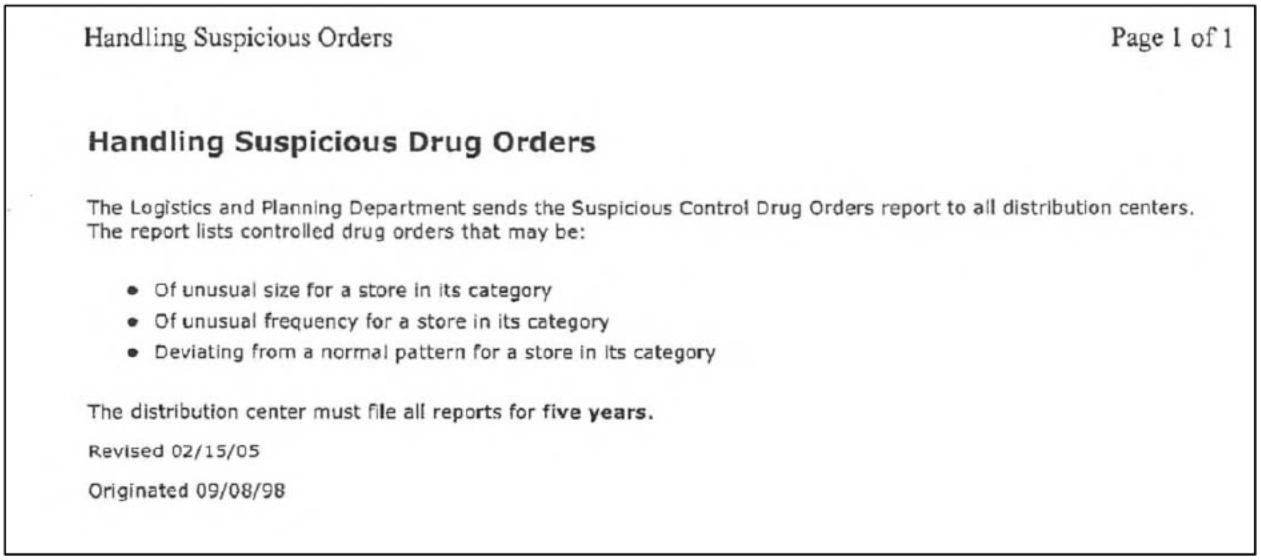
B. Walgreens Interactions with DEA re: 1301.74(b)

103. Walgreens repeatedly sought guidance from the DEA regarding its suspicious order monitoring process, over the course of many years. More importantly, Walgreens' communication with the DEA describes the suspicious order monitoring and reporting processes that Walgreens used. DEA repeatedly visited Walgreens' controlled substance Distribution Centers without identifying any complaints with Walgreens' suspicious order monitoring system. In 2006, Walgreens received its first notification from DEA, following a routine DEA audit, that DEA wanted changes made to Walgreens' suspicious order monitoring methods. Walgreens responded by updating its methods to follow the formula in Appendix E-3 of the Chemical Handler's Manual. In 2006, 2007, and 2008 Walgreens repeatedly informed DEA that it had done so. Additional DEA visits to Walgreens' Distribution Centers occurred in 2009 and 2010, again without any DEA complaints of Walgreens' suspicious order monitoring system. This timeline is discussed in further detail below and demonstrates that Walgreens believed it was meeting its regulatory requirements around suspicious order reporting using the Appendix E-3 methodology. It is my opinion based on my analysis in Sections VI, VII, VIII, and IX that Walgreens was in compliance with the DEA's suspicious order monitoring regulation, as well as the obligation to maintain effective controls against diversion more generally.

1. Early Years

104. In Walgreens' earliest available Suspicious Order Monitoring Standard Operating Procedures, from at least 1998, Walgreens sent Suspicious Control Drug Order reports to the DEA, where the report reflected orders of unusual size, frequency, or pattern:[182]

[182] Deposition of Edward Bratton, December 16, 2018, pp. 41-43 and Exhibit 5 at WAGFLDEA00001854 (Handling Suspicious Drug Orders Policy); see also US-DEA-00025683 (December 27, 1988 Buzzeo Letter to Walgreens in which DEA approved Walgreens' proposal to identify excessive or potentially suspicious orders, above and beyond its reporting of monthly sales, "*based on an average monthly sales figure multiplied by an arbitrarily selected deviation factor which is one of the key elements in devising an effective reporting system.*")



Handling Suspicious Orders Page 1 of 1

Handling Suspicious Drug Orders

The Logistics and Planning Department sends the Suspicious Control Drug Orders report to all distribution centers. The report lists controlled drug orders that may be:

- Of unusual size for a store in its category
- Of unusual frequency for a store in its category
- Deviating from a normal pattern for a store in its category

The distribution center must file all reports for **five years.**

Revised 02/15/05

Originated 09/08/98

2. 2004 to 2010

105. In 2004 and 2005, three Walgreens Distribution Centers received DEA visits where no issues with Walgreens' suspicious order monitoring system were noted. In May 2004, the DEA visited the Walgreens Distribution Center in Jupiter, FL, and "*their review did not identify any issues*."[183] An audit by the DEA would have included a review of the Suspicious Order Monitoring System in place at the Jupiter Distribution Center. Records indicate that additional DEA visits to other Walgreens Distribution Centers that handled Schedule II and/or III controlled substances occurred in October 2004 and May 2005 at Woodland, CA and Mount Vernon, IL, respectively.[184] There is also no mention of issues with Walgreens' suspicious order monitoring system.

106. In March 2006, the Detroit Field Office performed an audit of Walgreens' Perrysburg, OH Distribution Center ("Perrysburg Distribution Center"), another Schedule II controlled substance distribution center.[185] Two months later in May 2006, the DEA sent a

[183] WAGMDL00757549 – 568 at WAGMDL00757549.
[184] WAGMDL00757511 – 513 at WAGMDL00757511 (Internal Audit Report – February 2008); WAGMDL00757569 – 570 at WAGMDL00757569 (Internal Audit Report – July 2008).
[185] Deposition of Deborah Bish, February 1, 2019, Exhibit 13 at WAGMDL00709510 (Perrysburg Letter of Admonition).

Letter of Admonition ("2006 LOA") to Walgreens stating its findings. Particular to Suspicious Order Monitoring, the DEA stated for the first time in years of audits that it had determined Walgreens formula was "*insufficient*."[186,187,188] This represented a change from long-established practice. The DEA's May 2006 letter stated that Walgreens should advise the Detroit field office of the action planned to address the issues raised in the letter, and to contact Barbara Dobric in that office with any questions.[189]

107. In July 2006, Walgreens provided its response to Ms. Dobric. Walgreens communicated that it was going to update its suspicious order monitoring criteria over the next six months to follow the formula in Appendix E-3 of the Chemical Handler's Manual:[190]

> *"1. Controlled Substance Suspicious Orders*
>
> *Walgreens is currently pursuing the necessary programming to modify this formula in accordance with the voluntary formula listed in Appendix E-3 of the DEA Chemical Handler's Manual. Walgreens expects that these programming changes will be completed and implemented within the next six (6) months."*

108. By at least April 2007, I understand that Walgreens had updated its system for monitoring suspicious orders based on Appendix E-3. In an internal Walgreens email dated April 3, 2007, Walgreens' current criteria for determining "*store's excess orders*"[191] for Schedule

[186] Deposition of Deborah Bish, February 1, 2019, Exhibit 13 at WAGMDL00709510 (Perrysburg Letter of Admonition).
[187] Deposition of Deborah Bish, February 1, 2019, Exhibit 14 at WAGMDL00709508 (Justin Joseph Memo RE Audit Preliminary Response – May 2006).
[188] Groupings of 25 customers were established based on the purchase history of controlled vs. non-controlled substances. The average order per-item of each controlled substance was determined and multiplied by a factor of 3. To the extent that any controlled substance order exceeded that figure, it was identified as a potential suspicious order.
[189] Deposition of Deborah Bish, February 1, 2019, Exhibit 13 at WAGMDL00709512 (Perrysburg Letter of Admonition).
[190] Deposition of Edward Bratton, December 16, 2018, Exhibit 21 at WAGMDL00387642 (July 28, 2006 Pinon letter to Dobric).
[191] WAGMDL00400357 (Soliva email to VanOverbake, April 3, 2007).

II drugs used the Appendix E-3 formula for reporting to the DEA.[192] The calculation was identified as the following:[193]

> CII-Drug Reporting Computation
>
> 1. The **Stores-Avg-Order** per item / per whse is calculated by using the total-warehouse-order-count / number of stores serviced.
> This is based on 13-months data, i.e. the last 12 months plus the current month reporting period.
> Example. For the reporting month of 12/2006,
> Data covers 12/2005 to 12/2006
>
> 2. The **Stores-Avg-Order** computed from #1 is multiplied by factor 3 to calculate for the **Purchase-Limit**.
>
> 3. A store with ordered-quantity in excess of the purchase-limit will be reported
> 3.1 For violation in 2 months in a row within the last 6 months. 2 months are shown in the report
> 3.2 For violation in excess of 2 months, but within the last 6-month period. All months with violation are shown in the report.
> 3.3 2 months of violation but not consecutive are not reported.

Stores with ordered quantities that exceeded the purchase limit two months in a row or greater than two months over a six-month period were reported as exceeding the purchase limit. Walgreens Pharmaceutical Integrity manager Edward Bratton, who testified as a corporate representative on behalf of Walgreens, testified that Walgreens provided Excess Order Reports to the DEA until 2012 under the formula provided in Appendix E-3.[194]

109. Following the implementation in at least April 2007, Walgreens sent multiple communications to the DEA that stated Walgreens used Appendix E-3 to identify potentially suspicious orders. For example, in June 2007, just a few months after Walgreens' implementation of Appendix E-3, Dwayne Pinon of Walgreens sent an email to Michael Mapes

[192] WAGMDL00400357 (Soliva email to VanOverbake, April 3, 2007).
[193] WAGMDL00400357 (Soliva email to VanOverbake, April 3, 2007).
[194] Deposition of Edward Bratton, December 16, 2018, pp. 144-145 and Exhibit 6 at WAGMDL00396010 (Chemical Handler's Manual); *see also* Walgreens' Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, dated February 19, 2019, pp. 12-17 regarding Response to Request No. 3 (identifies Bates numbers for over 5,000 Suspicious Control Drug Order Reports for Cuyahoga and Summit Counties).

at the DEA.[195] Mr. Pinon asked Mr. Mapes to "*clarify DEA's expectations with respect to reporting suspicious orders of controlled substances*,"[196] and provided the language of 1301.74(b) and Appendix E-3. Mr. Pinon's email stated that Walgreens used the Appendix E-3 methodology because "*the Detroit DEA Office recently admonished Walgreens for not using this particular formula.*"[197] Mr. Pinon went on to describe the conversation with Mr. Mapes regarding suspicious orders and sought clarification upon what the DEA's expectations were for suspicious orders:[198]

> *"During our conversation, you indicated that DEA does not expect to receive reports which identify <u>all</u> suspicious transactions, but instead, only those transactions that the registrant cannot classify as not suspicious after review. Unfortunately, the regulation does not distinguish suspicious orders identified to the registrant from those that are reportable to DEA. In other words, I am unable to read into the regulation that the registrant must utilize a system to identify <u>potentially</u> suspicious orders and that only orders <u>confirmed</u> as suspicious must be reported to DEA. I would appreciate if you could confirm that this, in fact, is DEA's expectation." (emphasis original)*

In response, Mr. Mapes replied that "*the controlled substance suspicious order regulations does (sic) not provide detailed, specific guidance…*"[199] Mr. Mapes did not state that Walgreens' reliance on Appendix E-3 did not comply with regulatory requirements.

110. Seeking additional guidance from the DEA, on March 26, 2008, Mr. Pinon sent another email to the DEA regarding suspicious order monitoring. Mr. Pinon indicated that he had recently met Lisa Sullivan of the DEA at an NACDS meeting. Mr. Pinon states that "*the Detroit DEA office recommended to our Perrysburg, Ohio distribution center that Walgreens use*

[195] WAGMDL00387635 – 637 (Pinon email to Mapes, June 27, 2007).
[196] WAGMDL00387635 – 637 at WAGMDL00387635 (Pinon email to Mapes, June 27, 2007).
[197] WAGMDL00387635 – 637 at WAGMDL00387636 (Pinon email to Mapes, June 27, 2007).
[198] WAGMDL00387635 – 637 at WAGMDL00387636 - 637 (Pinon email to Mapes, June 27, 2007).
[199] WAGMDL00387635 – 637 at WAGMDL00387635 (Pinon email to Mapes, June 27, 2007).

the formula in Appendix E-3 of the Chemical Handlers Manual…when determining whether a controlled substance order may be considered suspicious"[200] (emphasis in original). Mr. Pinon stated that his "*reading of Appendix E-3 confirms that this guidance may be somewhat ambiguous*."[201] To that end, Mr. Pinon asked for his information to be passed along to someone that could work with Walgreens on its current suspicious order reporting system.[202]

111. In April 2009, the DEA performed an on-site investigation at the Perrysburg Distribution Center.[203] Two months later, DEA sent a letter to Walgreens regarding that investigation and did not identify any issues with Walgreens' suspicious order monitoring system.[204,205]

112. Likewise, in an internal email dated September 8, 2010, Walgreens personnel reported that a DEA on-site review of the Walgreens Mount Vernon, IL Distribution Center identified no issues with Walgreens' suspicious order monitoring system: [206,207]

> *"Great news that the DEA just completed their on site review of Mt. Vernon and came away without any issues or citing of the operation. Per your call, the review and recap went well for the procedures, inventory and operation surrounding control [sic] drugs handled through our DC. Nice work Mt. Vernon team!"*

Furthermore, the DEA agents on-site did indicate to Walgreens personnel that it could stop sending the Suspicious Control Drug discs to the DEA field offices.[208] But they did not alert

[200] WAGMDL00387651 – 652 at WAGMDL00387651 (Pinon email to Sullivan, March 26, 2008).
[201] WAGMDL00387651 – 652 at WAGMDL00387651 (Pinon email to Sullivan, March 26, 2008).
[202] WAGMDL00387651 – 652 at WAGMDL00387651 (Pinon email to Sullivan, March 26, 2008).
[203] WAGMDL00493683 – 687 at WAGMDL00493683 (DEA letter re Perrysburg, June 25, 2009).
[204] WAGMDL00493683 – 687 at WAGMDL00493683-685 (DEA letter re Perrysburg, June 25, 2009). Violations related to controlled substances included improper completion of DEA 222 Order Forms and the Schedule II day-gate did not self-close or self-lock.
[205] WAGMDL00493688 – 691 (July 2009 Steve Kneller response to DEA).
[206] The Mt. Vernon Distribution Center handled Schedule III controlled substances and utilized the same suspicious order monitoring system as Walgreens' other distribution centers. WAGMDL00757569 - 570 at WAGMDL00757569 (Internal Audit Report – July 2008).
[207] WAGMDL00387641 (Martin email to Coughlin, September 8, 2010).
[208] WAGMDL00387641 (Martin email to Coughlin, September 8, 2010).

Walgreens that its suspicious order monitoring system and related reporting were not in compliance with regulations.

3. 2012 Order to Show Cause

113. In Mr. Rafalski's expert report for Plaintiffs, Mr. Rafalski focuses on an Order to Show Cause issued to Walgreens' Jupiter, Florida Distribution Center in September 2012. Mr. Rafalski says that "*...the DEA alleged that Walgreens's failure to sufficiently report suspicious orders was a systemic practice that resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone.*"[209] I disagree with Mr. Rafalski's conclusion that the Florida OTSC is evidence of a "*systemic practice*" within Walgreens Distribution Centers or its retail pharmacies for that matter.

114. First, the volume of prescription opioids dispensed by Florida pain clinics was a major problem experienced by most, if not all, distributors in Florida. In notes from a two-hour presentation to the National Association of Board of Pharmacy in November 2012 on "Prescription Drug Trafficking and Abuse," Mr. Rannazzisi reported that 43% of all oxycodone 30mg products dispensed in 2010 were in Florida.[210] To address the problem of Florida pain clinics acting as both prescribers and dispensers of prescription opioids, in October 2010, Florida pain clinics were no longer allowed to dispense Schedule II and III controlled substances. As a result of administrative actions by DEA in 2010 and Florida's legislative changes, distribution of oxycodone to dispensing practitioners declined at least 97.5% from over 8,000,000 dosage units in May 2010 to approximately 200,000 units in October 2010.[211] To fill prescriptions, patients then went to pharmacies, including Walgreens. In 2012, the DEA had taken 91 actions, 50

[209] Rafalski Report, p. 116.
[210] Deposition of Mike Bleser, December 20, 2018, Exhibit 5 at WAGMDL00658247 (Email RE DEA Meeting at NABP – November 2012).
[211] Statement for the Record of Michele M. Leonhart, Administrator of DEA, before Senate Subcommittee on Crime and Terrorism, May 24, 2011, p. 10 (https://www.dea.gov/sites/default/files/pr/speeches-testimony/2012-2009/110524_testimony.pdf).

orders to show cause, 21 ISO's, and 85 surrenders of license from independents.[212] Cuyahoga and Summit Counties, or even Ohio, did not have the same pain clinic issues experienced by Florida.

115. Second, out of over 800 retail pharmacies in Florida,[213] the OTSC made allegations against only six pharmacies. Six retail pharmacies located in Florida with large dispensing volumes of controlled substances over a limited time period of abrupt change ***does not*** indicate a "systemic" problem across all of Walgreens' operations. Moreover, an OTSC is a list of allegations or claims – not a finding of judgment.

116. Third, I have not seen evidence that any of the alleged activity in Florida mentioned in the OTSC actually impacted any residents of Cuyahoga and Summit Counties.[214,215,216,217]

---

[212] Deposition of Mike Bleser, December 20, 2018, Exhibit 5 at WAGMDL00658247 (Email RE DEA Meeting at NABP – November 2012).

[213] WAGMDL00387653 – 707 at WAGMDL00387663 (OTSC).

[214] The Rafalski Report cites to WAGMDL00387753 in Footnote 521 on p. 121 in support of the statement "*many individuals from Ohio…have travelled by carloads to …Florida to obtain prescriptions for oxycodone….*"; however, that document is a blank page. I think the cite may have meant to reference WAGMDL00387760, which is a pre-hearing brief stating expected testimony from DPM S. Langston about "*many individuals from Ohio, Kentucky, and other states*" traveling to Florida pain clinics. This does not establish that any Prescription Opioids dispensed from a Walgreens Florida retail pharmacy ended up in Cuyahoga or Summit Counties.

[215] The Rafalski Report cites to WAGMDL00387941 in Footnote 521 on p. 121 in support of the statement "*detailing suspicious Florida dispensing to Ohio customers*"; however, this document does not discuss Ohio. I think the cite may have meant to reference WAGMDL00387946 – 947, which is a pre-hearing brief stating expected testimony from T. Benali about "*a resident of Chillicothe, Ohio, who obtained his prescription from a physician in Doral, Florida*." Chillicothe, Ohio, is in Ross County, Ohio – not Cuyahoga or Summit – and there was no mention of a Walgreens pharmacy.

[216] The Rafalski Report cites to WAGMDL00037521 in Footnote 520 on p. 121 in support of the statement "*Interstate 95 has been renamed the Oxycodone Express because of the brisk travel of people from Kentucky, Tennessee, [and] Ohio to South Florida to obtain medications*"; however, I think the cite may have meant to reference WAGMDL00037527, which is a footnote citing to testimony from Professor Doering in a CVS matter. This does not establish that any prescription opioids dispensed from a Walgreens Florida retail pharmacy ended up in Cuyahoga or Summit Counties.

[217] The Rafalski Report cites to WAGFLDEA00000459 in Footnote 518 on p. 121 in support of the statement "*For example, Pharmacy managers in Florida alerted their supervisors and the distribution center that they were ordering 55+ bottles a week (where 30 bottles was an admitted red flag) and that many of the prescriptions were coming from out of state.*" The only state referenced in the email is Tennessee, not Cuyahoga or Summit Counties in Ohio. The email is from a pharmacy manager seeking guidance from a pharmacy supervisor in July 2010 on the number of oxycodone 30 mg prescriptions at her pharmacy. Before filling these prescriptions, the pharmacy manager indicated she would check "*a drivers license matching name on rx, write down the diagnosis of patient on rx, and verify rx with Dr office.*" The pharmacy manager also indicated that she had caught 7 fraudulent prescriptions from three different patients and called local law enforcement. To me, this email

Nothing suggests that any Prescription Opioids dispensed at the six Florida pharmacies ended up in Ohio, let alone Cuyahoga or Summit Counties.

117. Fourth, from my review, Walgreens worked actively to address the volume of Prescription Opioids dispensed in Florida, including working with law enforcement. Per Walgreens documents, Walgreens noticed increases in Prescription Opioids dispensed by Walgreens pharmacies in Florida in the months before and after October 2010, when Florida law changed to prevent pain doctors from dispensing controlled substances. For example, in January 2011, shipments of oxycodone 30mg tabs were identified.[218] Walgreens initiated internal reviews of Walgreens Florida pharmacies starting in the first quarter of 2011.[219] At the same time, Walgreens personnel held regular meetings with DEA, state, and/or local law enforcement agencies starting in January 2011 through April 2012 to address the prescription opioid volumes. Meetings included training and best practices for dispensing legitimate prescriptions to patients, as well as cooperation with authorities.[220]

118. The charts below, disclosed to the DEA in a presentation by Walgreens in July 2012, show downward trends in dispensing of oxycodone 15mg/30mg, from January 2010 through June 2012 (first chart), and decreases in the shipments of 8 selected drugs from the Jupiter Distribution Center to the top 100 Florida pharmacies from January 2011 through June 2012 (second chart).[221]

---

reflects that Walgreens was aware of the prescription opioid issue in Florida, conducted due diligence on prescriptions, and contacted law enforcement when identifying fraudulent prescriptions.

[218] E.g., WAGFLDEA00000846 – 51 (Email RE High Quantity Stores – January 2011) with WAGMDL00436802 (Drug Class Spreadsheet); WAGFLDEA00000852 – 62 (January 11, 2011 Martin email to Atwell re sales order history); WAGFLDEA00000714 – 715 (DEA-Walgreens meeting, August 2011); WAGFLDEA00000459 – 60 (Email RE Oxycodone 30 mg – July 2010).

[219] AR EX 155 / DOJ 0017101 – 102; WAGFLDEA00000696 (Florida Focus on Compliance, July 20, 2011).

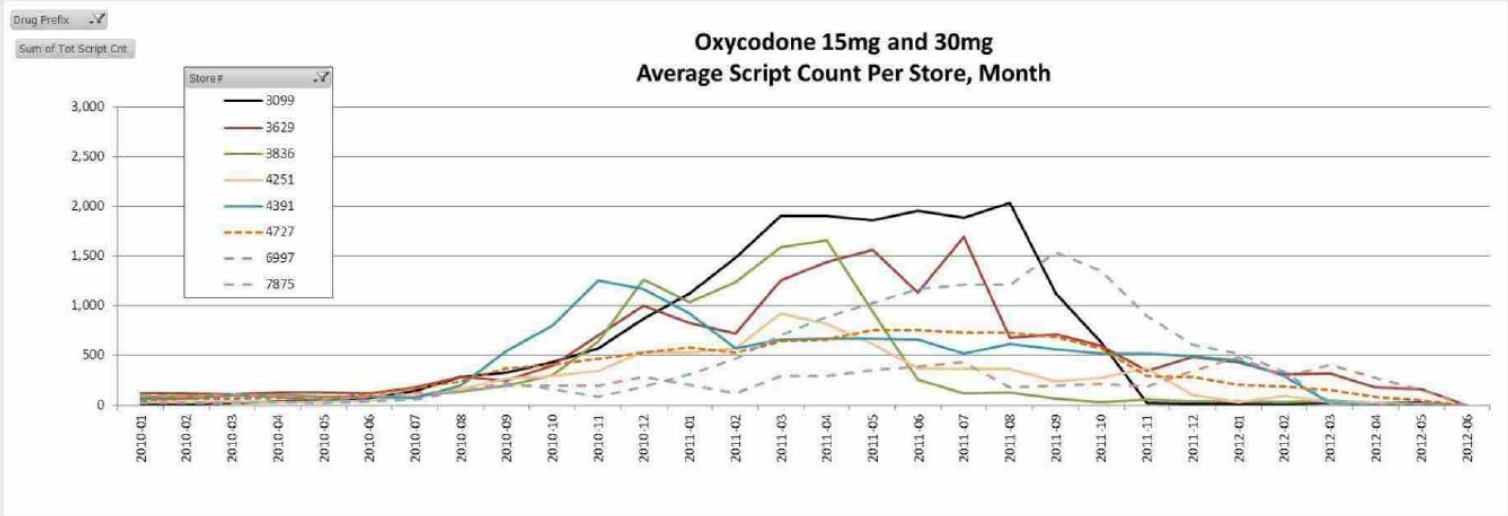
[220] E.g., WAGMDL00659828 – 856 (Walgreens presentation to DEA, July 17, 2012); WAGFLDEA00000716 – 720; WAGFLDEA00001348 (Controlled Substance Guidelines, January 18, 2012); WAGFLDEA00000741 – 762 (Guidelines for CII Dispensing and Best Practices, October 18, 2011); Deposition of Edward Lanzetti, January 14, 2019, pp. 10-11, 34; Deposition of Laurie Zaccaro, January 16, 2019, p. 12

[221] WAGMDL00659828 – 856 at WAGMDL00659848-849 (Walgreens presentation to DEA, July 17, 2012).

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

8 Florida Stores: Downward Trend in Oxycodone Dispensing

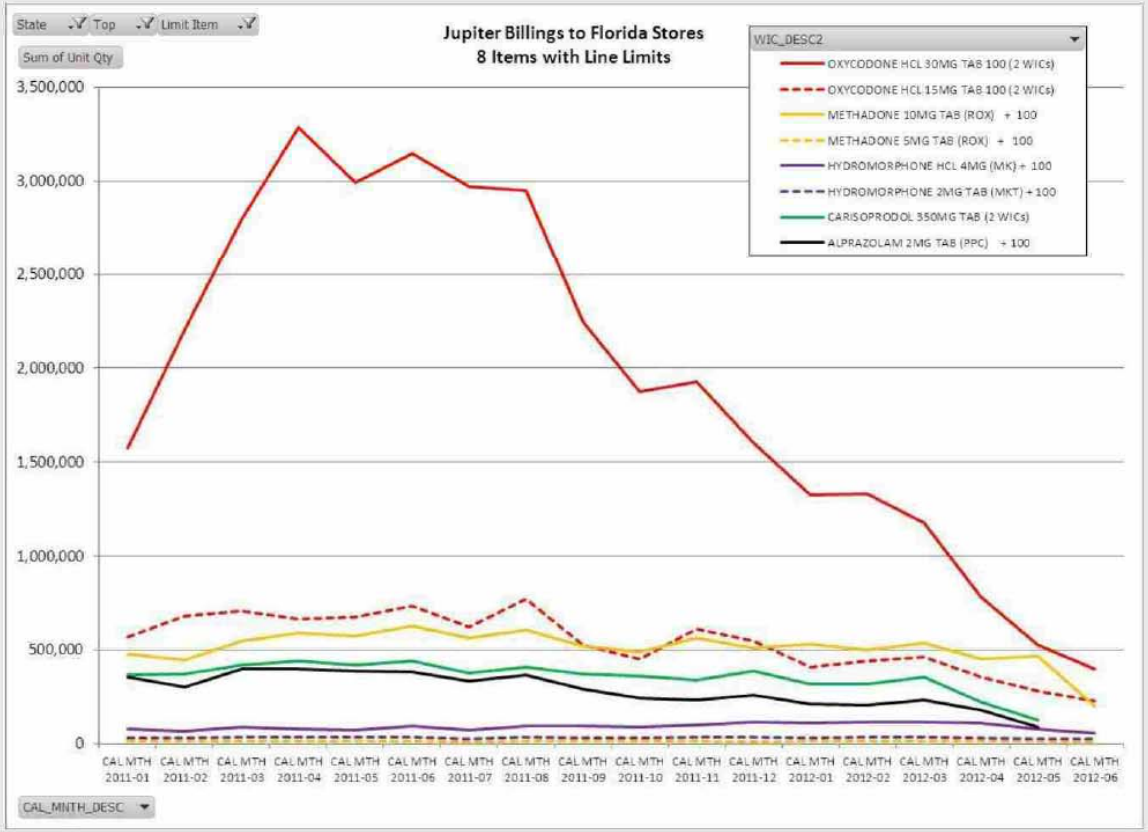
- 8 selected stores, average script count for Oxy 15 & 30



In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

Jupiter: Downward Trend for Selected Drugs

- Shipments of 8 selected drugs from Jupiter to top 100 Florida stores



As can be seen in the first chart, the average prescription count per store increased around October 2010, but by the end of 2011, all 8 stores' average prescription counts had declined to baseline levels. As seen in the second chart, the Jupiter Distribution Center's shipments of the largest of the 8 selected drugs, oxycodone 30mg, peaked in April 2011 and then declined over the remainder of 2011. The other seven selected drugs also declined over 2011. The DEA issued the OTSC in September 2012, well after the volume of controlled substances dispensed or shipped had **declined significantly**.

119. Finally, Walgreens entered into a settlement agreement with the DEA to resolve the claims in Florida.[222] Following that settlement, Walgreens engaged in rigorous self-evaluation to ensure that it was meeting the heightened standards it committed to as part of the agreement, including with respect to suspicious order monitoring, reporting, and other record keeping and related commitments.[223]

120. In summary, Walgreens had obligations to both mitigate diversion of controlled substances and to fill prescriptions for patients with legitimate medical needs. In balancing both of these obligations in Florida over a time period of legislative change that led to significant prescription volumes at pharmacies, Walgreens worked with law enforcement leading up to the OTSC in September 2012 to reduce the volumes of Prescription Opioids, and oxycodone 30mg in particular, dispensed by its retail pharmacies. Based on my review of the evidence, Walgreens did its best to deal with a difficult situation in conjunction with law enforcement and the DEA—a situation unlike that in other parts of the country such as Ohio. For all of these reasons, I disagree with the administrator's conclusion in the OTSC that there were "systemic" problems at Walgreens.

[222] WAGMDL00490963 – 978 (Settlement Agreement – June 2013).
[223] *See* WAGMDL00674321 – 45 (Internal Audit Report – December 2014).

4. 2013

121. Between February 4, 2013 and February 5, 2013, the Perrysburg Distribution Center was served with an administrative inspection warrant and seven subpoenas by the DEA.[224,225] No corrective actions were taken against the Perrysburg Distribution Center related to the administrative inspection warrant or subpoenas served in February 2013. Of note, the DEA's website on "*Knowing Your Customer/Suspicious Orders Reporting*" still referenced the Chemical Handler's Manual and Appendix E-3 as guidance for suspicious order reporting as late as March 2013.[226]

122. Since at least April 2007, Walgreens' identification and reporting of suspicious orders was based on guidance from DEA as found in Appendix E-3 of the Chemical Handler's Manual, on DEA's "*Knowing Your Customer/Suspicious Orders Reporting*" website, and based on feedback from DEA Detroit Field Office personnel. Although DEA personnel were alerted in multiple instances by Walgreens that its suspicious order monitoring system utilized Appendix E-3, the DEA did not communicate back to Walgreens that its system did not comply with the regulations until issuing an OTSC in Florida, during a unique period of opioid prescription abuse in one part of the country, following a legislative change that necessarily increased the volume of prescriptions at chain pharmacies. Prior to that unique situation, the DEA conducted audits of the Perrysburg and Mt. Vernon Distribution Centers in 2009 and 2010, respectively, without noting any issues with Walgreens' suspicious order monitoring system. Likewise, in the six years since Walgreens' settlement with DEA, DEA has not identified any issues with Walgreens' suspicious order monitoring. In my experience at Amneal, if the DEA did not identify any

[224] WAGMDL00493694 – 718 (Perrysburg administrative inspection warrant and subpoenas, February 4, 2013 and February 5, 2013).

[225] On February 15, 2013, Walgreens' outside counsel sent a letter to the Office of Chief Counsel at the DEA to extend another invitation to review Walgreens' enhanced suspicious order monitoring system and a recent Perrysburg controlled substance internal audit (WAGMDL00674277 – 279 at WAGMDL00674277-278 (First Latham letter to DEA, February 15, 2013)). On February 20, 2013, Walgreens' outside counsel sent a second letter to the Office of Chief Counsel at the DEA and Diversion Investigator Wayne Groves from the Detroit Field Office to request that the "*affidavit that contains the factual basis for the administrative inspection warrant and subpoenas*" be unsealed (WAGMDL00674280 – 281 at WAGMDL00674280 (Second Latham letter to DEA, February 20, 2013)). I understand that the affidavit has not been unsealed to-date and the DEA did not share any concerns about the Perrysburg Distribution Center with Walgreens.

[226] See Section VIII.F.

compliance issues through any of the following communications or actions—presenting a corrective action memo, an OTSC, or suspension of registration, after conducting its audits—it means the registrant is in compliance with regulatory requirements and has performed effective control over its controlled substance program. Furthermore, the DEA did not provide meaningful guidance for suspicious order monitoring even when it issued the Florida OTSC. DEA has considered identification and reporting of suspicious orders as a business judgment on the part of the distributor. In light of all of this, it is my opinion to a reasonable degree of professional certainty that Walgreens' use of Appendix E-3 to identify potentially suspicious orders until 2012 was in compliance with suspicious order monitoring and reporting regulations, as well as the CSA.

C. Walgreens' Development of CSR: 2008 to 2012

123. Walgreens began the design and implementation of a new Automated Controlled Substance Reporting ("CSR") system in 2008.[227] From 2009 through today, Walgreens rolled out versions of the new CSR that incorporated enhancements and other improvements. Indeed, according to Plaintiffs' hired expert Seth Whitelaw, Walgreens took meaningful efforts to meet its legal, regulatory, and societal obligations in this timeframe.[228]

124. In March 2008, Pharmacy Purchasing, Logistics, Legal, Loss Prevention, and Store Order System IT started the project with a "*goal…to build [a] system to prevent the… filling [of] any potential suspicious store order and to capture the data to identify stores with potentially suspicious activity for Loss Prevention team to investigate.*"[229]

125. A proposal circulated in June 2008 outlined the methodology for the new CSR.[230] The proposed system would use a methodology based on order size and order frequency to identify suspicious orders using Walgreens Strategic Inventory Management System

[227] WAGMDL00657563 – 566 at WAGMDL00657564 (History of SOM Development - April 2012).
[228] Deposition of Seth Whitelaw, May 16, 2019, pp. 401-402.
[229] WAGMDL00657563 – 566 at WAGMDL00657564 – 565 (History of SOM Development - April 2012); WAGMDL00659828 – 856 at WAGMDL00659845 (Walgreens presentation to DEA, July 17, 2012).
[230] Deposition of Edward Bratton, December 16, 2018, Exhibit 9 (2008 Bancroft Proposal).

("SIMS").[231] SIMS is Walgreens' inventory management program that automatically places product orders for Walgreens' retail pharmacies based on existing inventory levels in stores.[232] Rather than retail pharmacies having to place orders for all the items on its shelves, even non-prescriptions, SIMS efficiently tracks and re-orders stores' needs.

126. Under the new CSR, if a retail pharmacy's order exceeded "tolerance" or "frequency" limits established from using SIMS' historical data, the order would be flagged.[233] "Tolerance" limits would be used to monitor order size and would be established for each store/item combination.[234] "Frequency" limits would establish the expected number of weeks until the next order would be created; if an order was created before the expected date, the order would be flagged.[235,236]

127. There were five phases of roll-out from 2009 through 2012 that included continued modifications and updates to Walgreens' CSR:[237]

[231] Deposition of Edward Bratton, December 16, 2018, Exhibit 9 at WAGMDL00624503 (2008 Bancroft Proposal).
[232] Deposition of John Merritello, January 18, 2019, pp. 35-36.
[233] Deposition of Edward Bratton, December 16, 2018, Exhibit 9 at WAGMDL00624503 (2008 Bancroft Proposal).
[234] Deposition of Edward Bratton, December 16, 2018, Exhibit 9 at WAGMDL00624503 (2008 Bancroft Proposal).
[235] Deposition of Edward Bratton, December 16, 2018, Exhibit 9 at WAGMDL00624503 (2008 Bancroft Proposal).
[236] In November and December 2008, an internal audit of the Perrysburg Distribution Center was performed. The audit team "*recommend[ed] discussions continue with the cross-functional team consisting of the Logistics, Corporate and Regulatory Law, and Loss Prevention Departments…*" in furtherance of the requirement "*to have a process to disclose to the DEA any suspicious orders of controlled drugs that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery*" (WAGMDL00757193 – 211 at WAGMDL00757196 (Internal Audit Report – December 2008)).
[237] WAGMDL00667938 – 943 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process).

Review of CSR History

The CSR process has evolved through five phases since its inception in 2009. Each phase has expanded and improved the system's ability to identify and reduce excessive orders.

Phase	Key Points – Scope	Key Points – Identify/Flag selected orders	Key Points – Reduce order quantity for subset of flagged orders
1	• Deployed in August 2009 • Reviews WAG DC orders only • Review all Controlled Drug and PSE orders	• **Flags order based on by drug by store historical sales patterns, i.e. Tolerance threshold or order Frequency**	• No order reductions in Phase 1
2	• Deployed in September 2010 • No change to scope	• No change to Order Identification logic	• **Automatic reductions to orders that exceed Tolerance threshold**
3	• Deployed in June 2012 • **Relates vendor orders placed within 48 hours for same drug**	• Review and refinement of Tolerance/Frequency thresholds.	• No change in automatic order reduction logic
4	• Deployed in August 2012 • **Incorporates all Vendor orders and partial fills making them eligible for flagging and order reduction.**	• No change to Order Identification logic	• No change in automatic order reduction logic
5	• Deployed in November 2012 • Adds a Ceiling which limits the cumulative receipts of an item by a store	• Additional flags created for orders that are in excess of Ceiling for item/store combination • Remove Frequency threshold	• **Automatic reductions to orders that exceed either Tolerance or Ceiling threshold**

128. A CSR "pilot program" (referred to as Phase I) was launched in August 2009.[238] In this initial phase, the CSR utilized historical sales over the trailing 26 weeks to establish patterns for Schedule II through V controlled substances and pseudoephedrine.[239] The results from the Phase I roll-out demonstrated a "Proof of Concept" for continued advancing of the CSR.[240]

129. Phase II launched in September 2010. As reflected in the figure above, Phase II included an automatic reduction of orders that exceeded the tolerance threshold.[241]

[238] WAGMDL00492132 – 149 at WAGMDL00492136 (Controlled Substance Threshold Requirements Document).
[239] WAGMDL00667938 – 943 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process); WAGMDL00077016 – 023 at WAGMDL00077017 (PPT re Controlled Order Review Logic).
[240] WAGMDL00325172 – 186 at WAGMDL00325173 (Functional Requirements and Macro Design for Phase 3, April 6, 2012).
[241] WAGMDL00667938 – 43 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process); WAGMDL00077016 – 23 at WAGMDL00077017 (PPT re Controlled Order Review Logic).

130. The next three phases of the CSR rolled out from June 2012 to November 2012:

- In June 2012, Phase III was launched. This phase "*review[ed] and refine[d] Tolerance/Frequency thresholds.*"[242] Other changes included tracking orders placed by retail pharmacies with third-party distributors.[243] Any third-party orders would be reported to the CSR within 48 hours, along with information to identify the vendor order number, vendor number, order quantity, and the store user who placed an order.[244]

- In August 2012, Phase IV was rolled out.[245] In the two months since the Phase III launch, Phase IV combined outside vendor orders and partial order fills into the real-time CSR processes such that quantities exceeding the tolerance and frequency thresholds would be flagged and automatically reduced before shipping.[246]

- In November 2012, Phase V was launched. In Phase V, Walgreens updated the frequency threshold used based on a proposal from seven months earlier.[247] Phase V introduced "Ceiling Limits" to set a limit on "*the number of packages a store can receive over a given time period*" as predicted by the store sales

[242] WAGMDL00667938 – 43 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process).
[243] WAGMDL00325172 – 86 at WAGMDL00325174 (Functional Requirements and Macro Design for Phase 3, April 6, 2012).
[244] WAGMDL00325172 – 86 at WAGMDL00325174 (Functional Requirements and Macro Design for Phase 3, April 6, 2012).
[245] WAGMDL00667938 – 43 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process).
[246] WAGMDL00667938 – 43 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process); WAGMDL00492562 – 74 at WAGMDL00492564 (Functional Requirements for Macro Design for Phase 4).
[247] WAGMDL00007981 – 86 at WAGMDL00007981 (Bancroft proposal re ceiling limits, April 26, 2012).

history.[248] An example of how the algorithm would work was included in the proposal:[249]

> **How it would work:**
>
> Assume n = 6 weeks and P_n = 13. Thus in 6 weeks the store is allowed to order 13 packages.
>
> Further assume the a total of 9 packages were ordered in the last 5 weeks. Thus, if the store orders more that four packages (4 = 13 – 9) the store is flagged for the item/week. **Etc.**

131. Responsibility for using Phase V of the CSR was given to the newly formed Pharmaceutical Integrity group.[250] Unlike Phases II through IV, Phase V no longer simply reduced flagged orders to levels that met thresholds; in Phase V, all orders that exceeded a retail pharmacy's Ceiling Limit were eliminated from the system.[251] If a retail pharmacy wanted to increase its Ceiling Limit, it would have to submit a Controlled Substance Override Form and provide additional information regarding why an increase would be necessary for legitimate medical needs.[252] If an Override Form was submitted, the initial review would be performed by district pharmacy supervisor; if approved, members of the Pharmaceutical Integrity group would then review; if approved, the order would ship.[253]

---

[248] WAGMDL00007981 – 86 at WAGMDL00007981 (Bancroft proposal re ceiling limits, April 26, 2012); WAGMDL00667938 – 943 at WAGMDL00667940 (Presentation on Evolution of Controlled Substance Ordering Process).

[249] WAGMDL00007981 – 86 at WAGMDL00007984 (Bancroft proposal re ceiling limits, April 26, 2012). Before rolling out this proposed change in November 2012, Walgreens tested the Ceiling Limit criteria using historical sales data (WAGMDL00077016 – 23 at WAGMDL00077018 – 023 (PPT re Controlled Order Review Logic)).

[250] WAGMDL00528179 – 80 (Bleser Email RE SOM – September 2012).

[251] Deposition of Edward Bratton, December 16, 2018, pp. 272-273. In November 2012, an internal Walgreens email reported that a DEA presentation attended by Rex Swords of Walgreens instructed attendees to not reduce orders to acceptable threshold levels (WAGMDL00658246 at WAGMDL00658247 (November 8, 2012 Rex Swords email re Nov 8th DEA meeting at NABP)). I am not aware of any earlier guidance that Walgreens received to no longer cut orders.

[252] Deposition of John Merritello, January 18, 2019, pp. 108-109; Deposition of Edward Bratton, November 30, 2018, pp. 323-324; Deposition of Edward Bratton, December 16, 2018, pp. 272-273.

[253] Deposition of Edward Bratton, December 16, 2018, pp. 268, 272-273. For example, see WAGMDL00400360 (Flagged Order Detail).

132. If an Override Form was rejected, or an order was otherwise determined to be suspicious, the order would not be shipped, and Walgreens reported it to DEA.[254] I understand that there were no suspicious orders for prescription opioids from Walgreens' pharmacies in Summit or Cuyahoga counties following the transition to Phase V of the CSR.

133. Walgreens continued to make enhancements and improvements to its CSR after Phase V.[255]

134. Walgreens started the development of its CSR in 2008, with implementation of the first five phases occurring through November 2012. With each new phase deployment, Walgreens was modifying and updating the CSR to better identify and capture potentially suspicious orders to further anti-diversion controls. As Walgreens learned more from operating the CSR, Walgreens made adjustments that were dynamic and appropriate to keep up with trends in its business; e.g., adding third-party distributor orders, adding partial fill orders, creating Ceiling Limits, etc. Walgreens' development is consistent with the goals espoused by the DEA in not providing approval of or specific guidance on suspicious order monitoring systems. Again, by leaving suspicious order monitoring to each business's judgment, DEA wanted to accomplish the following:

- Make the industry more nimble at adapting to changes in drug abuse trends on the ground (e.g., hydrocodone to oxycodone to fentanyl).[256] SOM systems "*had to be able to react to new trends in diversion.*"[257]

- Different distributors created different styles of SOM programs. "*[I]t was understood, with the move toward the Suspicious Order Monitoring Program,*

[254] Deposition of Edward Bratton, December 16, 2018, pp. 273-275.
[255] For example, Walgreens was developing Phases V.V and VI in 2013 (Deposition of Steven Mills, November 8, 2018, Exhibit 9 at WAGMDL00308329 – 348 (Emails RE Review Application Screens and Proposed Changes); WAGMDL00491343 – 4 (Requirements for DEA Phase 6)).
[256] Deposition of Kyle Wright, February 28, 2019, pp. 117-118.
[257] Deposition of Kyle Wright, February 28, 2019, pp. 134-135.

that not every company would necessarily have the exact same type of program."[258]

- DEA "*wanted companies to be able to adopt their particular programs to whatever the particular clients were that they might service*."[259] Mr. Wright testified that was one reason why there were "*no set criteria or guidance put out by the DEA as to what should go into*" a SOM program.[260]

It is my opinion to a reasonable degree of professional certainty that Walgreens' CSR met the DEA's expectations and goals. As of March 2008, Walgreens began designing and operating its own, unique suspicious order monitoring system based on criteria established by the business's judgment and knowledge of its own retail pharmacies, in line with 1301.74(b). Not surprisingly, it took Walgreens a three-year period from its initial proof of concept in 2009 to complete Phase V. Walgreens is a large corporation with thousands of retail pharmacies that service patients with legitimate medical needs. Ensuring that adjustments to the distribution system did not impair the supply of medications for legitimate medical needs for so many patients is of major importance. DEA set no deadlines for registrants to complete new monitoring system criteria and expected any such changes to take some period of time.[261] Finally, while developing its new CSR suspicious order monitoring system, Walgreens continued to report potentially suspicious orders using the formula described in Appendix E-3 of the Chemical Handler's Manual.

D. Walgreens' Due Diligence

135. The Rafalski Report takes issue with Walgreens' due diligence: *"Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by Walgreens has generally been substandard at best…While I am aware that Walgreens claims it conducted due diligence via email, phone calls, or other undocumented*

[258] Deposition of Kyle Wright, February 28, 2019, p. 128.
[259] Deposition of Kyle Wright, February 28, 2019, pp. 128-129.
[260] Deposition of Kyle Wright, February 28, 2019, pp. 128-129.
[261] Deposition of Kyle Wright, February 28, 2019, pp. 123-125.

means, my review of the materials as referenced herein belie those claims, indicate that such actions rarely occurred, and that even when they did occur, they fell short of what is required."[262] In reaching this opinion, Mr. Rafalski ignores and/or mischaracterizes both the regulatory requirements and the evidence in the record.

1. Records Retention

136. Mr. Rafalski's criticism of Walgreens' due diligence rests heavily on his opinion that due diligence records for suspicious orders "*should be kept permanently*."[263] Based on my industry and enforcement experience, compliance with DEA regulations and guidance around maintaining effective controls against diversion does **not** require a distributor to **permanently** maintain due diligence documentation regarding a specific order, particularly after a distributor discontinues its distribution operations. The CSA and 1301.74(b) do not mention "due diligence" at all, much less do they require distributors to "permanently" maintain such records. This is consistent with Mr. Wright's testimony:[264]

> Q. Okay. And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence?
>
> THE WITNESS: No.

Mr. Rannazzisi agreed that there were not any requirements in the DEA regulations or guidance that due diligence documentation should be maintained for a certain period of time.[265] As such,

[262] Rafalski Report, p. 119.
[263] Deposition of James Rafalski, May 13, 2019, pp. 127-128.
[264] Deposition of Kyle Wright, February 28, 2019, p. 143.
[265] Deposition of Joseph Rannazzisi, May 15, 2019, p. 555.

Mr. Rafalski's opinion that due diligence records should be maintained permanently is wholly unsupported.

137. In fact, the only specified time period of record retention contained within regulations related to maintaining effective controls is 21 CFR § 1304.04 – Maintenance of records and inventories, which has a retention policy for "*at least 2 years from the date of such inventory or records.*"[266] From my experience while at Amneal, registrants were required to maintain at least two years of certain types of records. To the extent that a company's record retention policy exceeded two years, then the DEA could request those records. Walgreens, like many large corporations, has record retention policies.[267] For Monthly Suspicious Controlled Drug Reports, which were the Suspicious Drug Order reports sent to the DEA based on Appendix E-3, retention was for six years after the submission of the reports.[268] For documents related to its internal audit function, the records retention policy was three years.[269] After Walgreens stopped distributing controlled substances in 2014, there was no longer a business reason or a regulatory obligation to continue retaining those records indefinitely.

2. Mr. Rafalski Mischaracterizes Walgreens' Due Diligence

138. Notwithstanding Walgreens' record retention policy and lack of any regulatory requirement to permanently maintain due diligence records, Mr. Rafalski uses specific documents produced by Walgreens to support his claim that Walgreens performed no or poor due diligence. For documents that Mr. Rafalski cites to, he draws erroneous conclusions and/or mischaracterizes such documents. Furthermore, there are other documents not cited by Mr. Rafalski that provide additional examples of Walgreens performing due diligence. I will start my discussion below considering documents pre-dating 2012; then I will discuss documents in 2012 and after the formation of the Pharmaceutical Integrity group at Walgreens.

[266] 21 CFR § 1304.04.
[267] WAGMDL00286244 (Records Retention Policy).
[268] WAGMDL00286244 at p. 22, 45, 137 (Records Retention Policy).
[269] WAGMDL00286244 at p. 28 (Records Retention Policy).

139. First, the Rafalski Report criticizes Walgreens for a lack of pre-2012 due diligence documents. For example, the Rafalski Report cites to WAGFLDEA00000459 in Footnote 499 on p. 117 in support of the statement "*For example, limited pre-2012 emails produced by Walgreens reveal that the 'warehouse' (Walgreens DC) would call stores to inquire about large orders, but those orders would be cleared if the store confirmed that they were intentionally placed.*"[270] Mr. Rafalski's characterization of this document is misleading, as it does in fact demonstrate due diligence was performed. The email is from a pharmacy manager seeking guidance from a pharmacy supervisor in July 2010 on the number of oxycodone 30 mg prescriptions at her pharmacy.[271] In her email, she notes that "*This past week the warehouse called me to inquire about the growing orders of oxy 30 I have been placing, and said that it is a 'red flag' of sorts when a store orders more than 30 bottles per order.*"[272] In her email, the pharmacy manager described the steps performed to verify the legitimacy of out-of-state prescriptions before filling:[273]

> Brandon and I have agreed that we will only fill if they produce a drivers license matching name on rx, write down the diagnosis of patient on rx, and verify rx with Dr office. Every week I increase my order of oxy30 and every week I run out as more and more people are coming. I have caught a total of 7 fraudulent rx's from 3 different patients (in the last 2 months), the last patient was arrested and had a bail set at $50,000. I have called the Ocala police, the Marion county sheriffs office here as well as the Broward sheriffs office, the DEA, and to be quite honest, no one really seems to take my reports that seriously (except for this last week when the fake rx man was arrested). They promise to come and interview me and look at the data I have collected, but thus far no follow up. The bottom line is I want to make sure I am covering myself so no one thinks I (or Brandon) are doing anything unethical or illegal.

Before filling these prescriptions, the pharmacy manager indicated she would check "*a drivers license matching name on rx, write down the diagnosis of patient on rx, and verify rx with Dr office.*" The pharmacy manager also indicated that she had caught 7 fraudulent prescriptions from three different patients and called local law enforcement. This email exchange does reflect that Walgreens had an effective Suspicious Order Monitoring program in place as the

[270] Rafalski Report, p. 117.
[271] WAGFLDEA00000459 – 460 (Email RE Oxycodone 30 mg – July 2010).
[272] WAGFLDEA00000459 – 460 (Email RE Oxycodone 30 mg – July 2010).
[273] WAGFLDEA00000459 – 460 (Email RE Oxycodone 30 mg – July 2010).

Distribution Center identified the increase in oxycodone orders and contacted the pharmacy for due diligence. In my opinion, based on my work at Amneal, the steps shown by Walgreens in this example shows good due diligence, above and beyond what is required in the CSA or the regulations. Walgreens Distribution Centers contacted a customer pharmacy regarding a potentially suspicious order. The customer's explanation on the steps taken to ensure prescriptions were legitimate was appropriate. The customer's actions and responses indicate to me that proper verifications and medical necessity checks were performed. The customer was ensuring legitimate medical needs were being met by writing down the diagnosis of the patient on the prescription and verifying the prescription with the doctor's office. The other steps indicate that the Walgreens customer went over and beyond their obligations. Based on this due diligence transaction, I would have made the business judgment to ship to this customer.

140. There are other pre-2012 emails that were produced by Walgreens that demonstrate due diligence being performed, but do not appear in Schedule I of the Rafalski Report.[274] For example, Douglas Healy, Pharmacy Supervisor in Melbourne, Florida, sent a summary email of a meeting held with Walgreens pharmacy personnel and Dr. Charles Stark in November 2011.[275] The purpose of the meeting with Dr. Stark was to "*discuss[] his policies and procedures at this clinic*" for pain management.[276] Dr. Stark threatened legal action over Walgreens Pharmacy Manager Pat Paquette's refusal to fill Dr. Stark's prescriptions, despite the meeting held with Dr. Stark.[277] Mr. Healy alerted his supervisor of the Mr. Paquette's continued refusal to fill Dr. Stark's prescriptions:[278]

[274] Mr. Rafalski testified that the documents he reviewed are either cited in his report or Schedule I of his report (Deposition of James Rafalski, May 14, 2019, p. 796).
[275] WAGFLDEA00000763 – 765 (Email from Douglas Healy dated 11/18/2011).
[276] WAGFLDEA00000763 – 765 at WAGFLDEA00000765 (Email from Douglas Healy dated 11/18/2011).
[277] WAGFLDEA00000763 – 765 at WAGFLDEA00000764 (Email from Douglas Healy dated 11/18/2011).
[278] WAGFLDEA00000763 – 765 at WAGFLDEA00000763 (Email from Douglas Healy dated 11/18/2011).

> Tomas,
> I met with Dr. Stark last week along with a pharmacy manager of mine, Pat Paquette. The highlights of the meeting are below and I was going to send out to my district after running it by Dr. Stark.
>
> After the meeting, Pat still does not feel comfortable filling Dr. Stark's scripts for the following reasons:
> 1. He prescribes multiple controlled substances for each patient. At the meeting we shared with him documentation that drugs causing sedation should not be used together, or if they are, used sparingly. His reply was that "I treat patients, not protocols or recommendations." He also stated "I read somewhere that higher doses of Oxycodone cause hyper-excitability in about 1/2 of patients. However, I cannot find the document that was in." In other words, he has no documentation for his prescribing practices. He normally prescribes 180 tabs of immediate release Oxycodone, 180 Xanax 2mg and a muscle relaxer - Soma
> 2. The pain controlled substances prescribed, are immediate release. Notice I offered him some long acting alternatives in my email below....There is NO ACKNOWLEDGEMENT of this in his reply.
> 2. If you look at his license on the Fl license verification website, his specialty is PEDIATRICS. If we received a script from a currently practicing pediatrician for 180 tablets of Oxycodone, though a legal script, it would most likely be turned away because it's not in his/her scope of practice. Why should we treat a former pediatrician any differently. Futher, if questioned by law enforcement, what defense could we give for filling scripts from a pediatrician practicing pain management?

141. Not only did the Walgreens Pharmacy Manager meet with Dr. Stark as part of due diligence, he was still unsatisfied with the legitimacy of Dr. Stark's prescriptions and refused to fill based on Dr. Stark's license verification, immediate release formulations, and inability to identify supporting literature for his prescribing habits.

142. In another example, a Walgreens pharmacist in store #12885 in Palm Harbor, Florida[279] sent an email to Jackie Donovan, District Pharmacy Supervisor at Walgreens,[280] in September 2011 to summarize the policies and procedures that store applied to oxycodone prescriptions.[281] This included contacting the prescriber's office for verification and diagnosis, rarely filling only oxycodone prescriptions for a patient, filling only for residents living in the surrounding area (Palm Harbor, Oldsmar, Trinity, Clearwater, etc.), and refusing to fill for certain doctors' offices.[282]

[279] https://www.walgreens.com/locator/walgreens-2495+sandy+point+rd-palm+harbor-fl-34685/id=12885.
[280] DOJ 0015336 – 337 / AR Ex 146 (Email from Jackie Donovan dated 7/21/2011).
[281] WAGFLDEA00000401 (Email from Store #12885 dated 9/8/2011).
[282] WAGFLDEA00000401 (Email from Store #12885 dated 9/8/2011).

> Good Morning Jackie,
>
> I wanted to talk to you about the whole oxycodone situation and to let you know what we do here.
>
> 1) When filling any oxycodone medication we call and verify them as well as get a diagnosis, the purpose of this is to try and make sure that none of the rx's are fake to the best of our ability.
>
> 2) Also we rarely just fill oxycodone by itself. We ask for any other rx's that the md wrote for them and we verify with the md what scripts they gave them. (ie, long acting medication, anti-imflammtory,etc..) we don't just want to be filling just the oxy's (we understand there may be a few exceptions, but for the most part we make sure it is with some kind of therapy). If you are on a pain management regimen then we fell you should also have other medications to go with your treatment.
>
> 3) We also only fill for those that live in the area. (Palm Harbor, Oldsmar, Trinity, Clearwater, etc.)We also recommend that if you live in a different area to try a establish yourself with a pharmacy so that you are not driving around. We also do not take from certain md offices, as they have not been helpful or forthcoming with information that we ask. However we will fill for other md's that have done everything that we ask for.
>
> The biggest thing or complaint I get is #3. Not filling for brandton, tampa, springhill etc.. See I don't like to lie like alot of other stores and say we don't have. I tell them the true I am nice about it and they seem to understand until they "can't get" anywhere and then they call and complain that we would not fill their rx's (usually with a different story of course). I am sorry if you are getting calls on behalf of my store, that is something extra that I don't really want to put on you. But I figure that way they know and they won't come and bother us again next month. It will better help me control the situation so as it does not get out of control, but also be able to serve and help the patients that do come in
> and need the medication as well.

The pharmacist at this store was performing prudent due diligence in verifying legitimate prescriptions before dispensing oxycodone, recognizing that there was still an obligation to "*serve and help the patients that do come in and need the medication as well.*"[283] Furthermore, the pharmacist was seeking additional guidance as appropriate on other best practices that could or should be performed.[284]

143. In another example, a Walgreens pharmacist in New Port Richey, Florida,[285] emailed Amy Spiehs, District Loss Prevention Manager of Walgreens,[286] in August 2011 stating that he had refused to fill a prescription for oxycodone from a doctor located in Tampa, FL:[287]

[283] WAGFLDEA00000401 (Email from Store #12885 dated 9/8/2011).
[284] WAGFLDEA00000401 (Email from Store #12885 dated 9/8/2011).
[285] https://www.walgreens.com/locator/walgreens-7420+state+road+54-new+port+richey-fl-34653/id=5857.
[286] WAGMDL00387708 - 974 at WAGMDL00387940 (Appendix C of MOA).
[287] WAGFLDEA00000443 (Email from Store #05857 dated 8/26/2011).

From: Pharmacy Manager 05857
To: Amy Spiehs
Sent: Friday, August 26, 2011 4:41 PM
Subject: RE: OXY
Hi Amy,
I just turned down a oxy rx from tampa MD, the guy walked out saying "I hope you guys get robbed"

Hong 5857

The pharmacist alerted Walgreens loss prevention of his action to not fill a prescription from Tampa, FL that he deemed suspicious. This is acting on due diligence that indicated to the pharmacist that it should not fill that order.

144. In August 2011, Pharmacy Manager of store #04841 in Bradenton, Florida,[288] circulated an email to other Walgreens pharmacies regarding oxycodone and xanax prescriptions from pain clinics:[289]

From: "Pharmacy Manager 04841" [rxm.04841@store.walgreens.com]
Sent: 08/09/2011 01:39 PM CST
To: <district52rx@walgreens.com>; <district53rx@walgreens.com>; <district198rx@walgreens.com>; Chris Christopoulos
Subject: Medicaid Fraud-Please read!

I have had some questions about running prescriptions through insurance (especially medicaid) that are coming from these pain clinics that do not accept insurance. I called the Medicaid Fraud department and finally heard back from them today. She said that they have been working on this and she states we are NOT to run prescriptions, such as the oxycodones and xanax, through medicaid that come from these cash-only clinics. This is Medicaid Fraud and even though they do go through the insurance, we are not to run these through medicaid if we know these offices are cash-only clinics. The fraud department also gave me the annonymous Medicaid Fraud Tipline for us to call when a patient does go to these clinics and then tries to fill a prescription through their medicaid. The tipline number is 1-866-966-7226. If you have any questions, the local Medicaid department's phone number is 813-350-4800.

Thanks,
Ranad Judeh
04841

[288] https://www.walgreens.com/locator/walgreens-4210+e+state+road+64-bradenton-fl-34208/id=4841.
[289] WAGFLDEA00001160 (Email from #04841 dated 8/9/2011).

Ms. Judeh circulated the intelligence from due diligence efforts around dispensing controlled substances using insurance (especially Medicaid) when the prescriptions were written from cash-only pain clinics. This is also evidence of due diligence applied by Walgreens pharmacies.

145. Second, the Rafalski Report criticizes the Pharmaceutical Integrity group for allegedly doing little due diligence and failing to document it. The Rafalski Report cites to WAGMDL00107532 in Footnote 500 on p. 117 in support of the statement "*Even after the creation of the Pharmaceutical Integrity Department, Walgreens did little due diligence and did not keep complete records of any due diligence performed outside of a relatively small number of emails beginning in 2012.*"[290] Again, Mr. Rafalski mischaracterizes the document, which shows that in August 2012, a Controlled Substance Order Quantity Override Form was requested by a Walgreens retail pharmacy in South Carolina. A reason and detailed explanation for the override was provided on the form:[291]

> Reason: Other
>
> If you selected Other please enter reason here: High volume medication of choice by MD.
>
> Provide a detailed explanation of this request including Rx sales history 13 week item movement current on hand count inventory adjustments etc: 52 week item movement reports were analyzed by DLPS and RXS and were found to be consistent with no spikes. Numerous scripts were audited. All were found to be legitimate with proper DOS, appropriate time between fills (monthly), minimal cash pay, majority third party. no multiple pharmacy use, single prescriber writing scripts. This medication is the doctor's group drug of choice for treating patients suffering from both acute and long term pain conditions. My DLPS and myself both agree nothing looks out of the ordering with respect to the dispensing of this medication from the staff at 10329.

Contrary to Mr. Rafalski, in my reading of this correspondence, it is clear that due diligence was performed before deciding to approve the additional quantity. Not only was the annual history reviewed, but "numerous" prescriptions were audited for various criteria, with follow-up to the prescribers. Subsequently, in December 2012, the Walgreens pharmacist submitted a similar request. In response to this Controlled Substance Override request, Pharmaceutical Integrity made the additional due diligence request:[292]

[290] Rafalski Report, p. 117.
[291] WAGMDL00107532 – 33 (Mills Email RE Controlled Substance Order Override Form – August 2012).
[292] WAGMDL00107162 – 163 (Mills Email RE Controlled Substance Order Override Form – December 2012).

> Stephen,
>
> In order to process this request I require additional information of the top 5 MD's prescribing Hydrocodone 10/650MG.
>
> Information I'm looking for:
>
> - MD's DEA's Number/Address/Phone Number
> - MD's Scope of Practice
> - MD's affiliation with Hospitals or Independent groups
>
> Additionally, I would like to see the 3rd party VS. Cash sales for Hydrocodone 10/650MG. You may want to work with the DLPM to pull this report.
>
> If you have any questions, let me know.

Walgreens Pharmaceutical Integrity performed additional due diligence on the prescribing doctors and payor before approval. Again, this reflects proper due diligence by Walgreens.

146. The Rafalski Report also cites to WAGMDL00400358 in Footnote 501 on p. 117 in support of the statement "*Even after the creation of the Pharmaceutical Integrity Department, Walgreens did little due diligence and did not keep complete records of any due diligence performed outside of … sparse database notations about limited orders in and after 2013.*"[293] Walgreens ceased distributing all controlled substances to Cuyahoga and Summit Counties as of April 2014.[294] Thereafter, Walgreens had no obligation to identify and report suspicious orders subject to 1301.74(b).[295]

147. Nonetheless, Walgreens did produce its Controlled Substance Overrides from 2013 through 2018 and other documents that demonstrate continued due diligence and controls.[296] These documents are not identified in the Rafalski Report nor in his Schedule I. For example, in February 2013, a Walgreens pharmacy in Birmingham, AL submitted an override request for oxycontin 60mg.[297] The pharmacist indicates the prescription is for an oncology patient. Pharmaceutical Integrity responds that the store needs to follow the good faith dispensing policy, and asks questions about the patient's medical need for such a high dose. The pharmacist

[293] Rafalski Report, p. 117.
[294] Expert Report of Robert L. Brunner, May 10, 2019, p. 56.
[295] Although Walgreens does not have to have a suspicious order monitoring system since it does not distribute controlled substances, Walgreens still maintains its CSR.
[296] WAGMDL00400358 – 360 (Ceiling Override Report, Ceiling Limit Snapshot, and Flagged Order Detail).
[297] WAGMDL00415257 – 258 (Email from store #15144 dated February 21, 2013).

responds that the store is a new location with patients being acquired from a nearby CVS store, and the prescription was verified with the prescribing physician.[298]

-----Original Message-----
From: Koelz, Tammie
Sent: Thursday, February 21, 2013 11:03 AM
To: RxIntegrity
Subject: Re: Controlled Substance Order Quantity Override Form

This is a brand new store and all the patients are new to us at this location, we are pulling patients from the CVS up the street. Clarissa verified with the MD that this is an oncology patient and it is an increase over previous mess

Sent from my iPhone

On Feb 21, 2013, at 10:30 AM, "RxIntegrity" <RxIntegrity@walgreens.com> wrote:

> Tammie,
>
> Looking at the original hard copy at the store I do not see any GFD documentation. Please have the store follow through with the GFD policy. Also to note this patient has never filled this strength of Oxycontin at this store, this is a very high dose for someone who has never been on or filled this medication. I just want to make sure the store is following through and doing their due diligence.
>
> Be Well,
> Rx Integrity Team
>

This exchange indicates sound due diligence.

148. In March 2013, Pharmaceutical Integrity Manager Steven Mills responded to an inquiry from a Katy, TX,[299] pharmacy:[300]

Joy,

The store should not be manipulating their orders. If the store needs additional product you will need to fill out the controlled substance quantity override form found on the RxS homepage. If the store continues to manually increase or manipulate their orders we will report the store as suspicious to the DEA.

Be Well,
Steve

From the email above, it is clear that Walgreens took adherence to its policies and procedures for monitoring suspicious orders seriously.

[298] WAGMDL00415257 – 258 at WAGMDL00415257 (Email from store #15144 dated February 21, 2013).
[299] https://www.walgreens.com/locator/walgreens-411+s+mason+rd-katy-tx-77450/id=4696.
[300] WAGMDL00106996 – 998 at WAGMDL00106996 (Email from Steve Mills dated 3/5/2013).

149. In November 2013, a Pharmacy Manager from store #06574 in Lorain, Ohio,[301] sent an email to his Pharmacy Supervisor regarding two prescribers.[302] The email was then forwarded to Patricia Daugherty, Manager in Pharmaceutical Integrity,[303] for a prescribing analysis:[304]

> Hi Matt,
> Our stores filled [redacted] scripts for Dr. Potoczyk over the last 90 days, where [redacted] cripts were for controls. Out of that [redacted] were C2's and out of the [redacted] were for some form of Oxycodone. We have a new tool from IMS that also shows this prescriber wrote for [redacted] control scripts from a period July-Sep 2013. IMS does not capture every single pharmacy out there but they do include our data and some other independents/chains. According to their tool, he wrote for [redacted] controls [redacted] Oxycodone RXs (so our stores maybe fill about a third of his Oxy scripts) during that July-Sep time period were he wrote at least [redacted] total scripts, control and non-controlled. So he definitely ranks high and writes for a good number of controls in general.
>
> Our stores filled [redacted] total controls out of [redacted] scripts from Dr Hiti in the last [redacted] ays. IMS shows pharmacies they have data from filled a total of [redacted] cripts where [redacted] were for controls from July-Sep 2013. IMS shows he wrote for [redacted] Oxy scripts where we filled [redacted] but not during the exact same time period. Generally, Dr Hiti [redacted] Dr. Potoczyk but they are both up there for controls.
> What kind of concerns do our pharmacists have about their practices? Data may not necessarily mean anything since there are prescribers out there that are mainly pain management docs but they run a legitimate business with patients in real pain. It would be good to know if the stores have other information on these guys.
> Thanks

150. Ms. Daugherty utilized IMS prescribing data to analyze the types of prescriptions being written by the two physicians. After analyzing prescribing data, Ms. Daugherty requested any additional intelligence on the doctors from the pharmacists on the ground. This is sound due diligence.

151. In summary, from my review of documents cited by Mr. Rafalski and others outside of Mr. Rafalski's review, Walgreens performed due diligence procedures on potentially suspicious orders to resolve such suspicions before shipping or dispensing controlled substances.[305]

---

[301] https://www.walgreens.com/locator/walgreens-5411+leavitt+rd-lorain-oh-44053/id=6574.
[302] WAGMDL00049160 – 161 (Email from Lorain, OH pharmacy manager dated 11/8/2013).
[303] Deposition of Patricia Daugherty, November 15, 2018, p. 15.
[304] WAGMDL00049160 – 161 at WAGMDL00049160 (Email from Lorain, OH pharmacy manager dated 11/8/2013).
[305] Additional documents I reviewed that relate to Walgreens' performance of due diligence include (but are not limited to) WAGFLDEA00000829 – 841, WAGFLDEA00000863 – 864; WAGFLDEA00000999 – 1006; WAGFLDEA00001288 – 1327; WAGMDL00107473 – 474; WADMDL00107538 – 542; WAGMDL00311235 – 236; WAGMDL00415194 – 195; WAGMDL00305149 – 154; WAGMDL00104845 – 850.

3. Policies and Procedures

152. Walgreens also had policies and procedures in place to ensure that due diligence was conducted before orders shipped. Multiple Walgreens employees testified about these policies and procedures. The table below summarizes Walgreens employees that testified regarding the excess order quantity process ("Excess Order Quantity") and other diligence procedures used at Walgreens Distribution Centers starting in at least 2006:

Walgreens Employee	Tenure	Titles
Edward Bratton 30(b)(6)	2013-Present	Manager of Pharmaceutical Integrity - Southern Operations
Barbara Martin	1990-Present	Pharmacy Manager, Supervisor - Drug Database, Manager - Pharmacy Inventory Control
Douglas Peterson	2003-Present	IT Manager in Logistics
Jennifer Diebert	2003-Present	SAIL/C2 Coordinator and Supervisor - Perrysburg Distribution Center
Deborah Bish	2005-2013	C-II Function Manager - Perrysburg Distribution Center

The discussion below of the process used by Walgreens to identify orders of unusual size utilizes testimony given by these five Walgreens employees.

153. Mr. Bratton, Walgreens' 30(b)(6) witness, testified that by 2006-2007, Walgreens Distribution Centers employed policies and procedures that identified orders by retail pharmacies that were of unusual size.[306] The process utilized a combination of computer intelligence and human intelligence.

[306] Deposition of Edward Bratton, December 16, 2018, pp. 49-50, 94. This is consistent with testimony provided by Douglas Peterson (Deposition of Douglas Peterson, December 20, 2018, p. 310).

154. Walgreens Distribution Center personnel, often a SAIL coordinator, would run a daily query at each distribution center to identify orders of unusual size.[307] This was performed across all products at each distribution center, although the query for pharmacy items would not include any non-pharmacy products.[308] Each distribution center would set and update its own maximum quantity levels for all products, where that maximum quantity level would serve as a trigger to flag an order.[309] The flagged orders[310] would often be subject to a second query focused on the ordering history of the retail pharmacy.[311] If the order was in line with what the retail pharmacy usually ordered, the order would be shipped or modified and shipped.[312] If not, additional research would occur to verify the legitimacy of the order "*to make sure that…Walgreens wasn't shipping orders of excessive quantities or unusual size*."[313] The human intelligence gathering performed was generally via phone calls with the Walgreens retail pharmacy. Depending on the circumstance, the SAIL coordinator would escalate flagged orders to others within the Distribution Center for evaluation.[314]

155. Deborah Bish was the C-II Function Manager at the Perrysburg Distribution Center from approximately 2005 to 2013.[315] She provided additional insights into the process of filling an order for a Schedule II drug. Schedule II orders would first be reviewed in the computer room. For unusually-sized orders, the computer room would verify with the retail pharmacy that the order was accurate[316] "*to make sure that what they [Walgreens pharmacy] wanted – what*

[307] Deposition of Edward Bratton, December 16, 2018, p. 50.
[308] Deposition of Jennifer Diebert, January 24, 2019, pp. 36-38.
[309] Deposition of Edward Bratton, December 16, 2018, pp. 83-86, 94, 100; Deposition of Jennifer Diebert, January 24, 2019, p 37; Deposition of Douglas Peterson, December 20, 2018, p. 21.
[310] The daily report generated from the query were reviewed on the computer screen or printed (Deposition of Edward Bratton, December 16, 2018, pp. 94-95; Deposition of Jennifer Diebert, January 24, 2019, p. 36).
[311] Deposition of Jennifer Diebert, January 24, 2019, pp. 36, 93, 132; Deposition of Deborah Bish, February 1, 2019, p. 63 (Ms. Bish indicated she would call Barbara Martin for information on store order history).
[312] Deposition of Jennifer Diebert, January 24, 2019, p. 36; Deposition of Edward Bratton, December 16, 2018, pp. 50-51.
[313] Deposition of Jennifer Diebert, January 24, 2019, pp. 146, 294. Consistent with Mr. Bratton's testimony (Deposition of Edward Bratton, December 16, 2018, pp. 50-51).
[314] Deposition of Edward Bratton, December 16, 2018, pp. 91-92.
[315] Deposition of Deborah Bish, February 1, 2019, pp. 10-12.
[316] Deposition of Deborah Bish, February 1, 2019, pp. 62, 481-482.

they ordered was what they intended to order and to make sure they really needed it."[317] The results from such a query were generally viewed on a screen or were printed.[318]

156. After the computer room verified the order, the order would be released to the Walgreens Distribution Centers. Given their experience in filling orders for Schedule II drugs, pickers fulfilling the orders would notice atypical orders. Ms. Bish testified that any atypical orders would then be sent to her.[319] Ms. Bish would then engage in human intelligence gathering, usually in the form of phone calls to the retail pharmacy to verify the order's legitimacy.[320] To avoid having to leave the vault at the Perrysburg Distribution Center to make calls to the retail pharmacies, a telephone line was installed in the C-II vault.[321] As part of Walgreens Distribution Center's quality control process, an auditor would then review the order fulfillment by verifying the pick document with the products in the totes.[322] Again, based on the auditors' experiences, they would recognize orders that were out of the normal range.[323] To the extent any atypical orders were noticed by the auditors or the pickers, the orders would be sent to Ms. Bish for further review.[324] Ms. Bish would then conduct due diligence and engage the retail pharmacy for order verification and legitimacy.[325]

157. After Mr. Bratton's deposition, Walgreens located policy and procedure documents at Walgreens Distribution Centers that identified the procedures that were testified about by the Walgreens witnesses.[326] The testimony from the Walgreens employees is consistent with the standard operating procedure documents that were later located.[327]

[317] Deposition of Deborah Bish, February 1, 2019, pp. 62-63.
[318] Deposition of Deborah Bish, February 1, 2019, pp. 61-63.
[319] Deposition of Deborah Bish, February 1, 2019, pp. 481-483.
[320] Deposition of Deborah Bish, February 1, 2019, pp. 482-483.
[321] Deposition of Deborah Bish, February 1, 2019, p. 484.
[322] Deposition of Deborah Bish, February 1, 2019, p. 483.
[323] Deposition of Deborah Bish, February 1, 2019, p. 481.
[324] Deposition of Deborah Bish, February 1, 2019, p. 483.
[325] Deposition of Deborah Bish, February 1, 2019, pp. 483-484.
[326] Errata to Edward Bratton 30(b)(6) Deposition; WAGMDL00757788 (Rx Questionable Order Qty Procedure).
[327] Deposition of Edward Bratton, December 16, 2018, pp. 83-84; Deposition of Douglas Peterson, December 20, 2018, p. 21.

158. One such document was a "Quality System Procedure" for "RX Questionable Order Qty" dated December 11, 2006 for the Mt. Vernon Distribution Center.[328] The "*procedure cover[ed] the steps in verifying questionable store order quantities prior to order processing on RX items.*"[329] In other words, the process was to stop the shipment of products that were flagged as having "questionable" quantities until verification was made.

[328] WAGMDL00757788 (Rx Questionable Order Qty Procedure); Errata to Edward Bratton 30(b)(6) Deposition.
[329] WAGMDL00757788 (Rx Questionable Order Qty Procedure).

Walgreens
The Pharmacy America Trusts

Mt. Vernon Distribution Cent
Quality System Proced

Subject:	Orig	12/11/2006
II. RX Questionable Order Qty	Page	1 of 1
	Rev Date	N/A
Procedure Number	Revision	N/A
Approved By	Written By	Shelley Crisel

I. Purpose

A. To establish procedures for verifying questionable store order quantities on RX items.

II. Scope

A. This procedure covers the steps in verifying questionable store order quantities prior to order processing on RX items.

III. Procedure

A. Responsibilities of the computer room personnel and SAIL team.—Prior to Order Processing

1. Once transmissions have been received from the stores to its fullest, query name SCORDRSREV is printed for the next process cycle date to be reviewed. Any RX order greater than 24 skus of one item should print on query in store numerical order along with SS items.

2. The CR/SAIL personnel working the query will review the listing. If there is a questionable quantity, the pharmacy is contacted at that store and the order is questioned. If the order is incorrect, the original order for the item(s) is deleted and rekeyed correctly.

3. Once all orders have been reviewed for accuracy, computer room personnel is notified to kick off Order Processing.

B. Responsibilities of the RX team member personnel, Location Control and SAIL team—Stores Picking date

1. As RX team members are picking orders, if an order seems questionable, SAIL office will be contacted via phone for order accuracy verification.

2. SAIL team member contacts the pharmacy personnel at the store for order verification. If order is incorrect, a replenishment markdown is done on the billings by our Loc Control team and only the requested # of skus/cases is sent.

Consistent with Walgreens' employees' testimony, responsibilities for identifying questionable orders were divided between automated computer queries and human intelligence.

159. The RX Questionable Order Qty Procedure was updated as of April 8, 2010. In this update, additional steps were added, including responsibilities for Walgreens Company and assignment of training and enforcement responsibilities to managers.[330]

Walgreens
The Pharmacy America Trusts

Mt. Vernon, Illinois Distribution Center
Quality System Procedure

Subject:		**Orig**	12/11/2006
RX Questionable Order Qty		Page	1 of 2
		Rev Date	4/8/2010
Procedure Number	**Inventory Controls-1,2**	**Department**	SAIL
Approved By	Maurya Gill	**Written By**	Shelley Crisel

C. Responsibilities of Walgreens Company

1. Suspicious store orders and inquiries are handled through the Corporate Office Internal Audit Department.
2. Suspicious orders are then reported by Corporate to the FDA and/or DEA for controlled substances within 3 days.

IV. Training

A. To establish procedures that properly train, evaluate, and guide the team members on the process.

1. The SAIL Function Manager will be responsible for the training and enforcement of all procedures.
2. Training will be reviewed with all team members quarterly by the SAIL Manager.
3. Procedures will be reviewed with recommended changes made and policies updated.

Under the "*Responsibilities of Walgreens Company,*" the Corporate Office Internal Audit Department was to handle all "*[s]uspicious store orders and inquiries*" with reporting to authorities within 3 days.[331] I have not located other evidence regarding the extent to which the audit department may have handled suspicious orders.

[330] Deposition of Deborah Bish, February 1, 2019, Exhibit 8 at WAGMDL00751823 (Rx Questionable Order Qty procedure revised April 2010).
[331] Deposition of Deborah Bish, February 1, 2019, Exhibit 8 at WAGMDL00751822 (Rx Questionable Order Qty procedure revised April 2010).

160. Later in 2010, Walgreens deployed Phase II of its CSR system. In Phase II, orders that exceeded tolerance and frequency limits were automatically reduced to quantities that did not exceed the limit. In 2012, DEA shared its expectations with registrants that cutting quantities and shipping reduced orders, without investigation and potentially reporting to DEA, did not meet the requirements of 1301.74(b). In that same timeframe, i.e., fall of 2012, Walgreens implemented its Ceiling Limit tool, which cut potentially suspicious orders to zero and required additional investigation before the order could be placed. Controlled Substance Overrides were required to obtain quantities that exceeded Ceiling Limits established by the CSR. Starting in late 2012, the Pharmaceutical Integrity group was responsible for reviewing and approving requested overrides, among other tasks related to suspicious order monitoring. Finally, Walgreens stopped distributing controlled substances in 2014.

161. In addition to the diligence performed on store orders, Walgreens pharmacists and other employees at the store and district level reported potential diversion to law enforcement. Within Summit and Cuyahoga Counties, there are several examples of Walgreens retail pharmacists seeking law enforcement assistance with potential crimes related to prescription opioids. For example:

- In 2009, two suspects were arrested in a Walgreens pharmacy in Akron, OH due to a pharmacist's call to law enforcement over two fraudulent prescriptions for Percocet and Xanax:[332]

NARRATIVE

OFFICER NARRATIVE

The Pharmacist from Walgreen's, Nathan Goik, reported that two individuals had tried to pass two forged prescriptions, one for Xanax and the other for Percocet. He stated that both suspects, Dusty Richards and Tierra Ward walked up to the counter to present the prescription. It was in Ward's name and she provided her insurance card to him. Upon receiving the prescription, Goik was suspicious of the prescriptions. Goik contacted the Dr. on the prescription to verify if it was legitimate or not. Dr. Ghoubrial advised him that he had not written either prescription. The Pharmacist contacted Akron Police. When I arrived on scene, both suspects were seated in the pharmacy waiting area. Ward was read MIranda at 2043. Richards was read Miranda at 2120.

[332] AKRON_001158027 – 028 (Akron Police Report – July 2009).

- In 2013, Walgreens pharmacist Natalie Pancoe in Summit County contacted Detective Patrick Leonard regarding a suspicious prescription for a controlled substance:[333]

> 1. On Wednesday, November 6, 2013 at approximately 18:36 hours Det. Leonard received a call from Natalie Pancoe R.Ph. at Walgreens Pharmacy reference another fake prescription for Promethazine w/Codeine. Pancoe stated that a male caller had requested a prescription be transferred from a Target pharmacy in the Cleveland area.
>
> 2. Pancoe stated that the prescription was called in using Dr. Renee Rouweyha's name and DEA number from the Barberton Hospital Emergency Department. The phone number that was provided for Dr. Rouweyha was incorrect.

- In 2017, Ms. Pancoe again reported potentially suspicious prescriptions to Detective Leonard:[334]

> Message
> **From:** RXM 04776 [RXM.04776@store.walgreens.com]
> **Sent:** 4/13/2017 1:44:51 PM
> **To:** pleonard@akronohio.gov
> **Subject:** Dr. Lisy
>
> Detective Leonard,
>
> [redacted] prescribed Adderall, oxycodone, oxymorphone, soma, tramadol, and alprazolam by Dr. Todd Lisy.
>
> I also wanted to note her husband, [redacted] passed away [redacted] He was taking gabapentin, oxymorphone, Adderall, and oxycodone all prescribed by Dr. Lisy.
>
> The quantity and combination of medications does not seem appropriate to me.
>
> Thank you for looking into this for me. Let me know what you find out.
>
> Thank you,
>
> Natalie Pancoe

- In 2015, a Walgreens pharmacist notified law enforcement of an attempt to fill an illegitimate prescription for Percocet at Walgreens store #12444 in Cleveland, OH:[335]

[333] SUMMIT_001520592 – 596 (Akron Police Department Report of Investigation – November 2013).
[334] AKRON_000367619 (Ms. Pancoe April 2017 Email).
[335] CUYAH_007488966 – 979 (Cleveland Investigation – May 2016).

Offense Summary

The following information was obtained from the Cleveland Police Department Report: On 06/11/2015, Cleveland Police Department (CPD) Officers tasked with the enforcement of pharmaceutical drug laws was contacted by Walgreens Pharmacist Josh Close who reported that a female had attempted to fill a fraudulent South West General prescription for #120 Percocet 5/325 on a Dr. Shirley Bennett prescription paper. This prescription was verified as being fraudulent. This information was shared with WEB (West Shore Enforcement Bureau) Officers. Investigators determined that multiple fraudulent South West General prescriptions had been filled in the Cleveland area. Investigators agreed to conduct a joint investigation. This investigation revealed that numerous blank prescriptions had been taken from South West General Hospital by an employee who along with others filled or attempted to fill, forged or fraudulent prescriptions written for strong opiate based pain medication in the Cleveland area. Amanda Burns, the defendant, along with her co-defendants Sabrina Carr, Tracy Tomblin, and Jamie Mets all participated in this illegal activity to obtain prescription paper, create fraudulent prescriptions and fill those forged/fraudulent prescriptions.

After a lengthy investigation, it was revealed that fraudulent prescriptions had been filled at the Walgreens store #12444 located at 3415 Clark Avenue in Cleveland, Ohio, and received by [redacted] the defendant. The investigation revealed that on 08/02/2014, the defendant received 45 Oxycodone 5/325 pills and on 06/02/2014, she received 120 Percocet 05/325 pills. The Officer Manager for Dr. Shirley Bennett wrote in a written statement, "She (Dr. Bennett) does not write RX for Percocet over #30. [redacted]

162. Furthermore, Laurie Zaccaro, Asset Protection Manager at Walgreens, testified that she has worked jointly with the Ohio Board of Pharmacy to investigate thefts over the last 12 years.[336]

163. Finally, Walgreens witnesses testified that they had no knowledge of any diversion occurring at the Perrysburg Distribution Center, showing that Walgreens' diligence policies were effective. Ms. Bish, the C-II Function Manager at the Perrysburg Distribution Center testified:[337]

> *" Q. Do you have any personal knowledge of Walgreens ever shipping any orders of unusual quantities of controlled substances to Walgreens stores without first checking to see if those orders were justified?*
>
> *A. Not if they had the large quantities in there that alerted us, they would have always been checked.*
>
> *Q. Do you have any personal knowledge of Walgreens ever shipping controlled substances into any illegitimate channels?*
>
> *A. No.*

[336] Deposition of Laurie Zaccaro, January 16, 2019, pp. 12, 17-20, 60-61.
[337] Deposition of Deborah Bish, February 1, 2019, pp. 485-487.

Q. Do you have any personal knowledge of Walgreens ever shipping controlled substances to a Walgreens store that then diverted those controlled substances into an illegitimate channel?

A. No.

Q. We've talked about a number of steps in the ordering process where unusually large orders may have been brought to your attention.

A. Right.

Q. In that process did you take steps to make sure that Walgreens wasn't shipping unusually large quantities of controlled substances to the stores?

A. Yes, I would call the store and usually mark the order down because they didn't really want what they ordered, if it was an unusually large amount."

Ms. Diebert, who was responsible for Schedule III through V controlled substances at the Perrysburg Distribution Center, testified: [338]

" Q. Back when Walgreens was still distributing controlled substances, was it ever part of your job to make sure that Walgreens wasn't processing orders of excessive quantities of controlled substances?

A. It was.

Q. And when I say 'excessive quantities,' was it also part of your job to make sure that Walgreens wasn't shipping orders of unusual size?

A. Yes. We would look for any large orders and compare them against their history.

Q. Did you take steps in your job to make sure that at least as part of your job Walgreens wasn't shipping orders of excessive quantities or unusual size?

A. Yes.

[338] Deposition of Jennifer Diebert, January 24, 2019, pp. 58, 293-294.

Q. Do you have any knowledge of Walgreens ever shipping excessive quantities of any products to a Walgreens store?

A. I don't have any personal knowledge of that happening.

Q. Do you have any knowledge of Walgreens ever shipping controlled substances into illegitimate channels?

A. No, I don't."

164. In summary, Mr. Rafalski fails to consider multiple factors that ensured Walgreens Distribution Centers' due diligence and other policies prevented controlled substances from being shipped to illicit channels:

- Walgreens Distribution Centers did not distribute outside of its retail pharmacies. As discussed in Section IX.A, Walgreens Distribution Centers knew its customers and knew there were policies and procedures in place around Good Faith Dispensing, Inventory Controls, Recordkeeping, Training, and a number of other areas to avoid diversion. Further, evidence in the record supports that Walgreens pharmacists in Cuyahoga and Summit Counties reached out to law enforcement upon encountering questionable prescriptions.

- Walgreens Distribution Centers were not delivering product to rogue pain clinics or internet pharmacies, both of which were Mr. Rannazzisi's and the DEA's focus from at least 2005 through March 2013.

- Walgreens documents show due diligence occurring despite the fact that the regulations do not explicitly require the retention of documents into perpetuity. Additional due diligence was appropriately performed via telephone.

- Each distributor's decisions regarding the structure and components of its suspicious order monitoring system were subject to their discretion and judgment based on their business, provided the effective controls against diversion were maintained. As discussed later in Section X.C, Plaintiffs have not shown there

> was any public health epidemic attributed to diversion in Cuyahoga and Summit Counties due to Walgreens' distribution of controlled substances. To the contrary, Walgreens Distribution Center witnesses testified that they took steps to prevent diversion and that they had no knowledge of any suspicious orders shipping to a Walgreens store.

In my opinion, Walgreens had in place good due diligence procedures to identify and verify the legitimacy of suspicious orders before shipment. Walgreens' diligence went beyond what is required by the CSA and the implementing regulations, and, in fact, there is no evidence that any suspicious orders were shipped for an illicit purpose or into an illegitimate channel.

E. Conclusion

165. Per 21 USC § 823(b)(1) and (e)(1) and 21 CFR 1301.74(b), distributors were required to have anti-diversion controls, inclusive of a suspicious order monitoring system:

- "*maintenance of effective controls against diversion of particular controlled substances…into other than legitimate medical, scientific, research or industrial channels;*"[339]

- "*The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency*."[340]

[339] 21 USC § 823(b)(1).
[340] 21 CFR § 1301.74(b).

Distributors were required to maintain controls to keep pharmaceuticals within legitimate channels for medical, scientific, research, and industrial purposes. To assist in that, distributors were required to "design and operate" a system that would identify suspicious orders.

166. Based on my work performed in this matter and my industry experience, it is my opinion to a reasonable degree of professional certainty that Walgreens maintained effective controls against diversion for Cuyahoga and Summit Counties in light of its business model and customer base.[341] Using its judgment based on its knowledge of its customers, Walgreens designed and operated a suspicious order monitoring system to identify orders of unusual size, deviating from a normal pattern, and of unusual frequency prior to shipment. Further, Walgreens practiced due diligence procedures and automated procedures to eliminate suspicion by resolving flagged orders using its knowledge of its customers.

X. Additional Rebuttal of Plaintiffs' Experts

167. Mr. Rafalski offers the following opinion across all Defendants:[342]

- All Defendants "*failed to maintain effective control against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970]*"[343] *and "failed to design and operate a system to identify suspicious orders of controlled substances in violation of the security requirement set forth in 21 C.F.R. § 1301.74(b).*"[344]

[341] I also reviewed policies and procedures regarding Walgreens' physical security controls as required under 1301.72. From my review of its routine internal audits for controlled substances at its Distribution Centers, Walgreens had sufficient security controls to comply with regulations (WAGFLDEA00001747-766; WAGFLDEA00001776-795, WAGFLDEA00001796-811, WAGFLDEA00001812-829, WAGFLDEA00001830-853) (Controlled Substances Mini Audit Reports: June 2010 – February 2012).
[342] Rafalski Report, p. 7. In his deposition, Mr. Rafalski testified that he did not provide any opinions related to Anda. Deposition of James Rafalski, May 14, 2019, p. 840.
[343] Rafalski Report, p. 120.
[344] Rafalski Report, p. 121.

- "*This systematic failure [to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market] was a substantial cause of the opioid epidemic plaguing the country and specifically in Cuyahoga County and Summit County.*"[345]

168. In reaching these opinions, Mr. Rafalski claims to rely on 1) documentation and testimony produced by Defendants, 2) analyses performed by Dr. McCann, and 3) his experience as a diversion investigator, including undisclosed legal guidance he says he received from DEA lawyers.[346] However, for the reasons discussed below, Mr. Rafalski's and Dr. McCann's analyses performed and opinions reached specific to Walgreens are unreliable as they are based on mischaracterizations of documents and/or misleading analyses.

A. Mr. Rafalski's Opinions Only Relate to Oxycodone and Hydrocodone

169. From my review of Mr. Rafalski's report and his deposition, Mr. Rafalski offers opinions specific to Walgreens only regarding oxycodone and hydrocodone.[347] As such, Mr. Rafalski has provided no basis to draw any conclusions related to any other controlled substances.

B. Walgreens Ceased Distributing Controlled Substances

170. Walgreens Distribution Centers supplied Walgreens retail pharmacies in Cuyahoga and Summit Counties with oxycodone and hydrocodone from at least August 1, 2002.[348] As discussed above, Walgreens entered into a long-term distribution agreement with AmerisourceBergen in March 2013 to supply all prescription drugs to Walgreens retail pharmacies.

[345] Rafalski Report, p. 7.
[346] Deposition of James Rafalski, May 14, 2019, p. 695.
[347] Tables pertaining to Walgreens are on pp. 41-46 of the Rafalski Report. Charts pertaining to Walgreens are on pages 45-56 in Schedule II of the Rafalski Report (Rafalski Report, p. 121).
[348] Expert Report of Robert L. Brunner, May 10, 2019, p. 42.

171. The last shipment of oxycodone by a Walgreens Distribution Center to a Walgreens retail pharmacy in Cuyahoga or Summit Counties was on March 4, 2013.[349] The last shipment of hydrocodone by a Walgreens Distribution Center to a Walgreens retail pharmacy in Cuyahoga or Summit Counties was on April 9, 2014 and April 4, 2014, respectively.[350] All of Walgreens' distribution of controlled substances likewise ceased in 2014.

172. After this time, any controlled substance orders that were shipped to Walgreens retail pharmacies in Cuyahoga or Summit Counties were distributed by distributors other than Walgreens. I understand that claims in this matter are brought against distributors and manufacturers of prescription opioids. Any analyses, such as Appendix 11 of the McCann Report, that present shipments to Walgreens retail pharmacies that were distributed by non-Walgreens Distribution Centers are not appropriate for determining which orders Walgreens was obligated to monitor and report under § 1301.74(b). Walgreens' regulatory obligations as a distributor, including under § 1301.74(b), ceased when Walgreens stopped distributing controlled substances. Accordingly, Mr. Rafalski and Dr. Whitelaw both testified that they have no opinions about Walgreens' suspicious order monitoring system after Walgreens stopped distributing controlled substances.[351]

C. Plaintiffs Failed to Establish a Causal Link Between Alleged Suspicious Orders and the Opioid Epidemic

173. Mr. Rafalski opines that Defendants' suspicious monitoring systems were a "*substantial*" cause of the opioid epidemic both nationally and within Cuyahoga and Summit Counties. However, Mr. Rafalski's analysis lacks the basis or foundation to support such an opinion.

174. Even assuming (erroneously) that Mr. Rafalski did identify suspicious orders placed by a Walgreens pharmacy to a Walgreens Distribution Center, he did not establish that any suspicious order distributed by Walgreens to retail pharmacies in Cuyahoga or Summit Counties

[349] Rafalski Report, p. 132.
[350] Expert Report of Robert L. Brunner, May 10, 2019, p. 56.
[351] Deposition of James Rafalski, May 14, 2019, p. 561. Deposition of Seth Whitelaw, May 16, 2019, pp. 432-433.

were diverted into illicit channels. In other words, neither Mr. Rafalski nor Dr. McCann established that any controlled substance *orders* ended up in illicit channels. To make such a determination, Mr. Rafalski would have had to analyze specific suspicious orders. However, Mr. Rafalski admitted that he did no such thing:[352]

> *Q: You didn't do any analysis to see whether any specific suspicious order caused the diversion of any specific pills, correct?*
>
> *A: I think that's an accurate statement.*

175. Not only did Mr. Rafalski not analyze any specific suspicious order to show diversion, he also has no opinion of whether any specific order that was flagged resulted in harm to a person:[353]

> Q. You have no opinion about whether any particular order that was flagged as suspicious led to someone's addiction, overdose or death, correct, sir?
>
> A. As of today, I have no opinion on that matter.

176. Mr. Rannazzisi testified that "*when you have diversion and these drugs are – are going out into the community and getting into the wrong hands, the drugs are being used without supervision. The drugs are being abused. It causes overdose, that causes death.*"[354] I agree with Mr. Rannazzisi that diversion into illicit channels can cause death and is negative for communities; however, there is no evidence that any orders distributed by Walgreens Distribution Centers to Walgreens retail pharmacies in Cuyahoga and Summit Counties were actually diverted. Mr. Rafalski and Dr. McCann have not even attempted to show that any such

[352] Deposition of James Rafalski, May 14, 2019, pp. 469-470.
[353] Deposition of James Rafalski, May 14, 2019, p. 508.
[354] Deposition of Joseph Rannazzisi, May 15, 2019, p. 426.

evidence exists. Presumably if such evidence existed, they would have pointed to it. In the *Southwood Pharmaceuticals* case and the *Masters Pharmaceutical* case, actual incidents of diversion of orders or pills were identified. In each instance, an investigation of the alleged harm/wrongdoing occurred to establish links to the source that allegedly enabled such harm/wrongdoing. As to Walgreens, there is nothing to suggest anything similar occurred. Mr. Rafalski and Dr. McCann have nothing to say at all about what happened to Walgreens' shipments after they arrived at the pharmacies. There is no evidence whatsoever that shipments by Walgreens Distribution Centers to Walgreens retail pharmacies led to diversion, which led to the opioid epidemic in Cuyahoga and Summit Counties.

D. Mr. Rafalski's Reliance on Aggregate Volumes of Shipments Does Not Establish that Walgreens Did Not Maintain Effective Controls

177. Mr. Rafalski opines that Walgreens Distribution Centers "*failed to maintain effective control against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].*"[355] In support of this opinion, the Rafalski Report states:[356]

> The bar graphs identified as Figures 45-56 in Schedule II to this report demonstrate a clear escalation of prescription opioids into Cuyahoga County and Summit County by dose, base weight and MME.The massive increase in prescription opioids without a documented basis is indicative of a failure to maintain effective control.

178. The bar graphs used by Mr. Rafalski to "*conclude that several of the defendants in this case had a 'massive increase' or 'escalation' of opioids distribution*"[357] are from Appendix 9 of the McCann Report. Mr. Rafalski attaches 65 charts in Schedule II to his report, out of 3,877 total pages in Dr. McCann's Appendix 9. Of these 65 charts, pages 45 to 56 of Schedule II are specific to Walgreens. These charts specific to Walgreens identify shipments of all oxycodone and hydrocodone by Walgreens Distribution Centers to all Walgreens pharmacies located in Cuyahoga or Summit Counties. Mr. Rafalski points to the volume of shipments as

[355] Rafalski Report, p. 120.
[356] Rafalski Report, p. 121.
[357] Deposition of James Rafalski, May 14, 2019, p. 535. Mr. Rafalski answered yes to this question.

indicative of failed controls. In my opinion, the charts in Mr. Rafalski's Schedule II or Dr. McCann's Appendix 9 do not demonstrate ineffective controls. All that these charts show is ***volume***.

179. None of the charts in Appendix 9 of Dr. McCann's report and relied upon by Mr. Rafalski provide any information to establish actual diversion. These charts are nothing more than aggregate levels of oxycodone and hydrocodone shipments to ***all*** Walgreens pharmacies in the two Ohio Counties, which would reflect distribution to a legitimate channel. Nothing can be gleaned from these charts about the potential for diversion at any individual Walgreens pharmacy.

180. Even if Mr. Rafalski's report had included charts showing the volume of shipments at individual pharmacies, that still would not be enough, on its own, to identify diversion. As Detective Leonard of Akron, OH confirmed, he personally has never started an investigation related to diversion based solely on the volume of prescriptions being written or the volume of prescription opioids being dispensed. Per Detective Leonard, "*[t]here's always more factors that are looked at before an investigation is opened*" as volume alone cannot tell you that something is wrong.[358] From my experience in designing and operating an effective anti-diversion program at Amneal (including suspicious order monitoring), charts of this nature provide minimal, if any, insight into diversion or suspicious orders:

- These charts do not show that any prescriptions filled by any pharmacies in Cuyahoga or Summit Counties were not for legitimate medical reasons.

- These charts do not show the distribution of any particular drug strength to any particular pharmacy in Cuyahoga or Summit Counties.[359] Despite Mr. Rafalski's testimony that certain products, like oxycodone 30mg, are more "*highly*

[358] Deposition of Patrick Leonard, May 23, 2019, pp. 427-428.
[359] Walgreens performed such analyses in evaluating stores. For example, see WAGMDL00659828 – 856 at WAGMDL00659847 and – 849 (Walgreens presentation to DEA, July 17, 2012).

abused,"[360] there is no such analysis performed in these charts, or elsewhere in Dr. McCann's or Mr. Rafalski's work.

- The charts in Appendix 9 of Dr. McCann's report and Schedule II of Mr. Rafalski's report do not identify any orders that were flagged by Dr. McCann as allegedly suspicious[361] -- i.e., these bar graphs do not show suspicious orders flagged by McCann.

- These charts do not show any patterns of how specific pharmacies in these counties order controlled substances or certain groups of controlled substances together. Mr. Rafalski testified he had relied on such patterns as **a potential** sign to investigate while he was at DEA, but he performed no such analysis here.[362] (emphasis added)

- These charts do not provide any basis to ascertain the frequency with which specific pharmacies may be ordering to detect if there are any suspicious orders.

- These charts do demonstrate the normal flow of business in the pharmaceutical industry, albeit in the aggregate across all Walgreens' stores in two counties. The peaks and lows are indicative of an active market. If you look at the patterns you will see the peaks are typically followed by decreases in volume. Moreover, suspicious order monitoring systems are not designed to prevent legitimate business growth. In my experience from working at Amneal, the changes in volume in Walgreens' shipments over time reflect normal inventory management not potential diversion or failure of effective control.

[360] Deposition of James Rafalski, May 13, 2019, p. 64 and May 14, 2019, p. 720.
[361] Mr. Rafalski acknowledges this (Deposition of James Rafalski, May 14, 2019, pp. 535-536). Moreover, Mr. Rafalski testified that he looked at less than 10% of the charts in Dr. McCann's Appendix 9 and included 65 pages in Schedule II of his report (Mr. Rafalski testified that he reviewed 200 – 300 charts out of Dr. McCann's 3,877 pages (Deposition of James Rafalski, May 14, 2019, p. 542)).
[362] Deposition of James Rafalski, May 13, 2019, pp. 64-65. Walgreens performed such analyses as part of its due diligence; e.g., see WAGMDL00659828 – 856 at WAGMDL00659848 – 850 (Walgreens presentation to DEA, July 17, 2012).

181. Mr. Rafalski's opinion is that poor controls and ineffective suspicious order monitoring systems leads to diversion. However, his whole analysis rests on looking at volumes shipped to pharmacies – but all he is capturing is inventory. The charts attached to Mr. Rafalski's report in Schedule II do not provide any information about the legitimacy of the actual prescriptions being filled or any diversion of oxycodone or hydrocodone. In the Rannazzisi letters, Mr. Rannazzisi indicated that suspicious orders include orders of unusual size, deviating substantially from normal patterns and unusual frequency. Both Mr. Rafalski and Dr. McCann did not use the 21 C.F.R. 1301.74(b) regulation as described by Mr. Rannazzisi in their analysis or opinion in reaching their conclusions on Walgreen's SOMP.

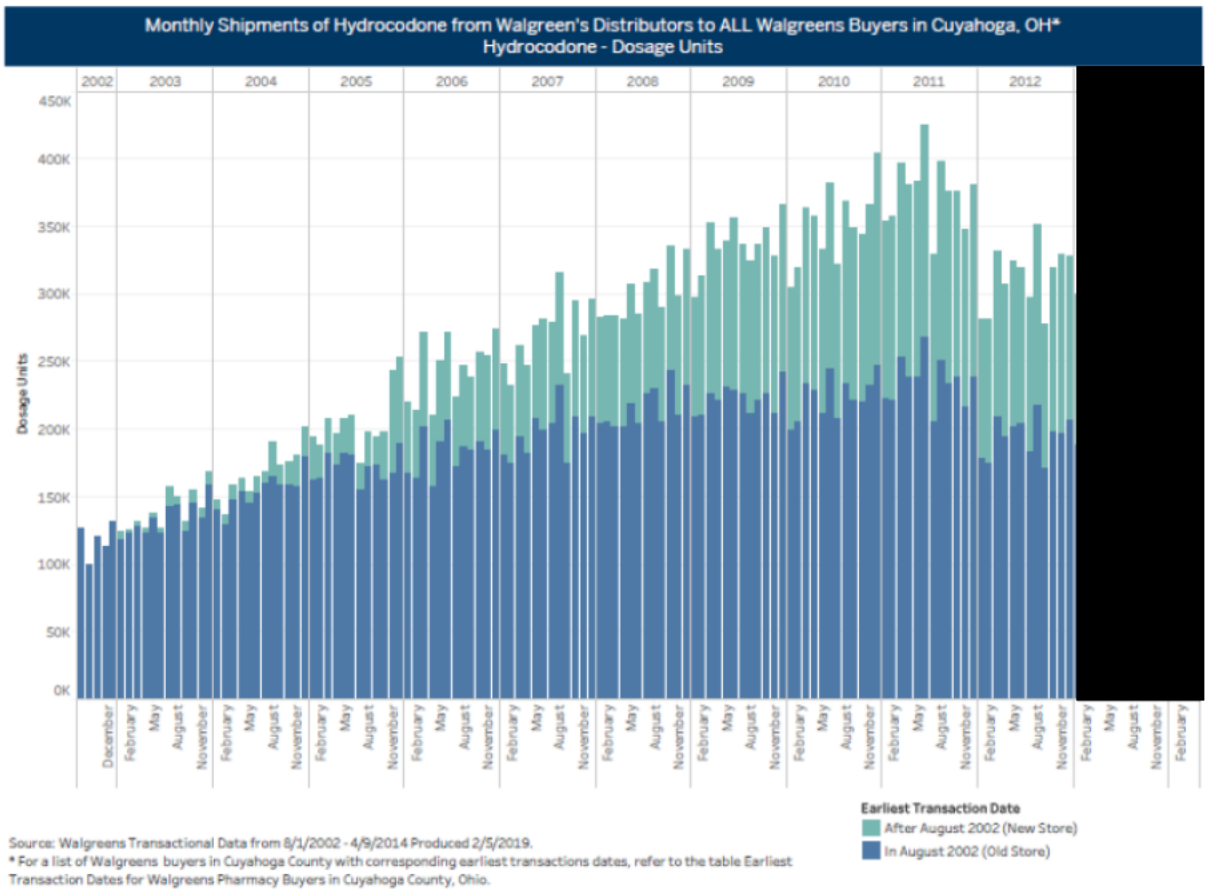
182. Moreover, aggregating the data in the fashion that Dr. McCann has in his charts is misleading for various additional reasons, some of which are discussed below.

1. Nearly 50% of the Walgreens Stores in Cuyahoga and Summit Counties are New Stores

183. Mr. Rafalski relies on county-wide charts of volumes of oxycodone and hydrocodone by Walgreens Distribution Centers to (erroneously) opine that Walgreens failed to maintain effective controls, and thus, diversion occurred.[363] These charts do not separate stores that existed as of August 1, 2002 (the start of transactional data produced by Walgreens), referred to as "Old Stores," from stores that opened after August 1, 2002, referred to as "New Stores." The Brunner Report analyzed the same aggregate volume data for shipments of hydrocodone (and oxycodone) into Cuyahoga (and Summit) County by Walgreens Distribution Centers, but separated the volumes related to Old Stores and New Stores:[364]

[363] For example, see Rafalski Report, Schedule II at Fig. 46.
[364] Expert Report of Robert L. Brunner, May 10, 2019, p. 35 and Appendix E at p. 13.

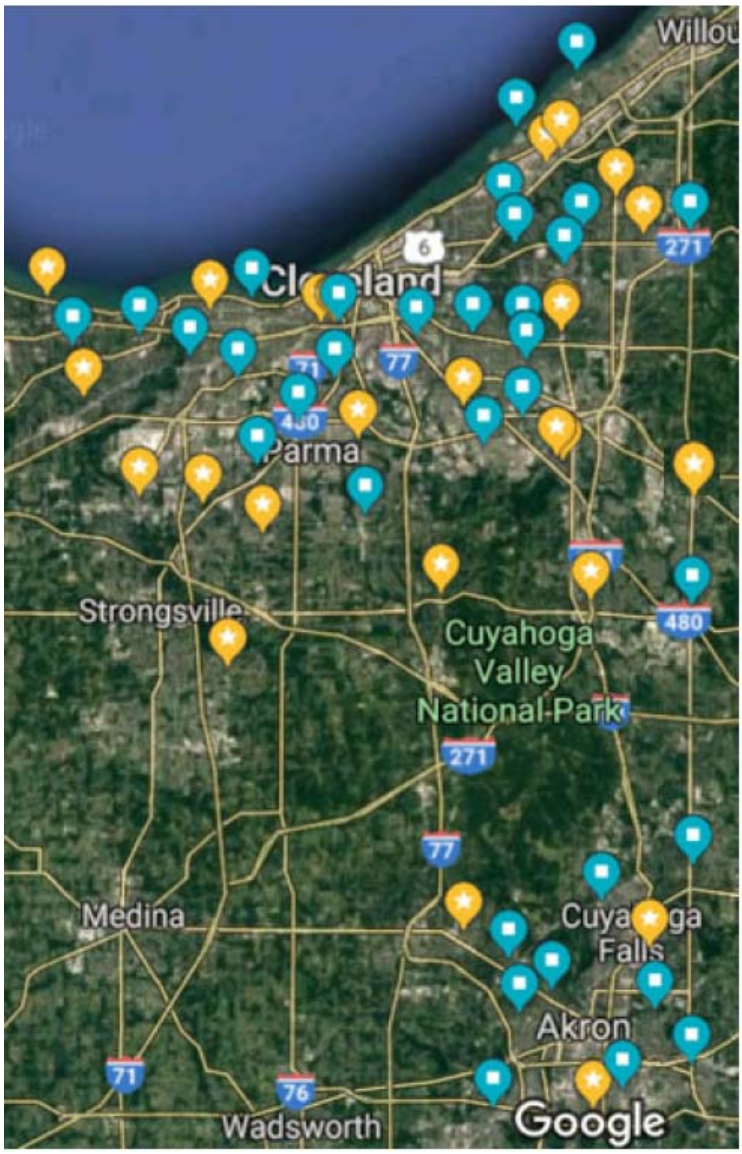
Figure 14 - Old Stores (dark blue - bottom) and New Stores (teal - top)



In Mr. Brunner's chart, using the same data as Mr. Rafalski, it becomes clear that the vast majority of the volume growth comes from the addition of New Stores. The aggregation of data for all stores in the county without any effort to track trends on a store-by-store, drug-by-drug basis misleads the reader and is unreliable for drawing the conclusion that Walgreens lacked effective controls. Again, reliance on volume data alone fails to establish diversion, especially when presented in the aggregate.

184. As discussed in Section V.B, Walgreens has been re-locating stores or opening new stores to capitalize on more visible and convenient locations to increase sales volumes of all products sold within the retail pharmacies. From the Brunner Report, I understand that 26 of the 59 Walgreens stores that operated in the distribution timeframe (2002 to 2014) were new stores

that opened in Cuyahoga and Summit Counties since August 1, 2002.[365] In the image below, blue stores were in existence as of August 1, 2002 ("Old stores"); yellow stores opened after August 1, 2002 ("New stores").[366] There are 33 Old stores (blue) and 26 New stores (yellow).[367]



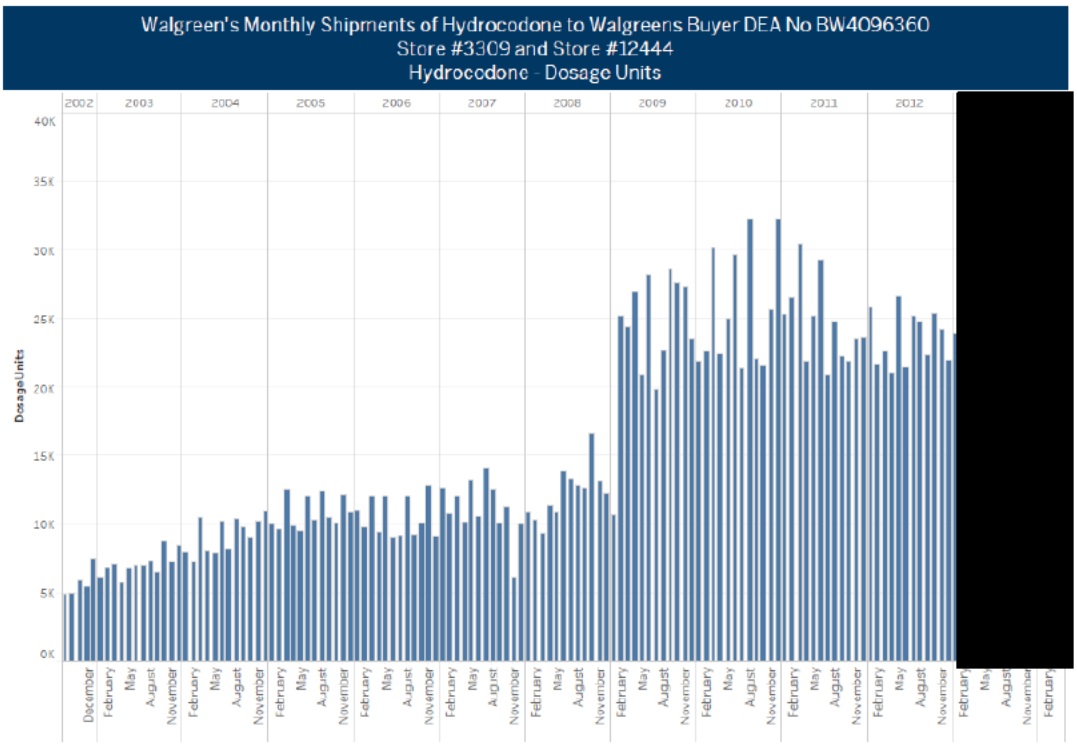
[365] Expert Report of Robert L. Brunner, May 10, 2019, Appendix E at pp. 17-18.
[366] Brunner Supplemental Materials, "Map Screenshots – New and Old Stores Together.pdf".
[367] Expert Report of Robert L. Brunner, May 10, 2019, Appendix E at pp. 17-18.

185. Also from the review of Mr. Brunner's supplemental materials, the map views of the New Stores demonstrate that the New Stores are typically located at busy intersections or large streets, have ample parking with easy access in and out, and/or are free-standing buildings, often with a drive-through window.[368] The New Stores locations are selected to capitalize on such characteristics in order to drive greater traffic into stores to generate increased sales of all products.[369]

186. In certain instances, the DEA registration number of a New store stayed the same as the number for an Old store. Dr. McCann's analysis of the ARCOS and Walgreens transaction data failed to capture such situations. The Brunner Report identifies three pairs of stores with the same DEA registration number with different physical locations, but were treated as the same store by Dr. McCann.[370] One example is discussed within the Brunner Report: the relocation of Walgreens store #3309 from 3121 Clark Avenue, Cleveland, OH to 3415 Clark Avenue, Cleveland, OH.[371] At the new location, the store number became #12444.[372] Store #3309 closed on January 28, 2009 and Store #12444 opened on February 1, 2009.[373] In the chart below from the Brunner Report,[374] which is a re-creation of Dr. McCann's chart that combined stores #3309 and #12444, a significant increase in volume of hydrocodone occurred in February 2009 – coinciding with the opening of store #12444, at a new location on a much bigger intersection:

[368] Brunner Supplemental Materials, "Map Screenshots – New Stores.pdf".
[369] Conversation with John Merritello.
[370] Expert Report of Robert L. Brunner, May 10, 2019, p. 35 and Appendix F.
[371] Expert Report of Robert L. Brunner, May 10, 2019, p. 40.
[372] Expert Report of Robert L. Brunner, May 10, 2019, p. 41.
[373] Expert Report of Robert L. Brunner, May 10, 2019, pp. 39-40.
[374] Expert Report of Robert L. Brunner, May 10, 2019, p. 38.

Figure 16 - McCann's chart above, excluding Non-Walgreens distributors, but before correcting for his combination of two distinct stores (#3309 and #12444)



Not surprisingly, after the opening of Store #12444, the volume of hydrocodone shipments increases given the new and improved location of Store #12444. After all, the relocation would have intended to capture growth impacts across all store items from advantageous location characteristics. Per the map below, Store #12444 is located on a large intersection, is a free-standing building, and has easy in-and-out access, including a drive-through window:[375]

[375] Expert Report of Robert L. Brunner, May 10, 2019, p. 40.

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

Figure 19 - Map showing the locations of the Old Store and New Store that share the same Buyer DEA Number

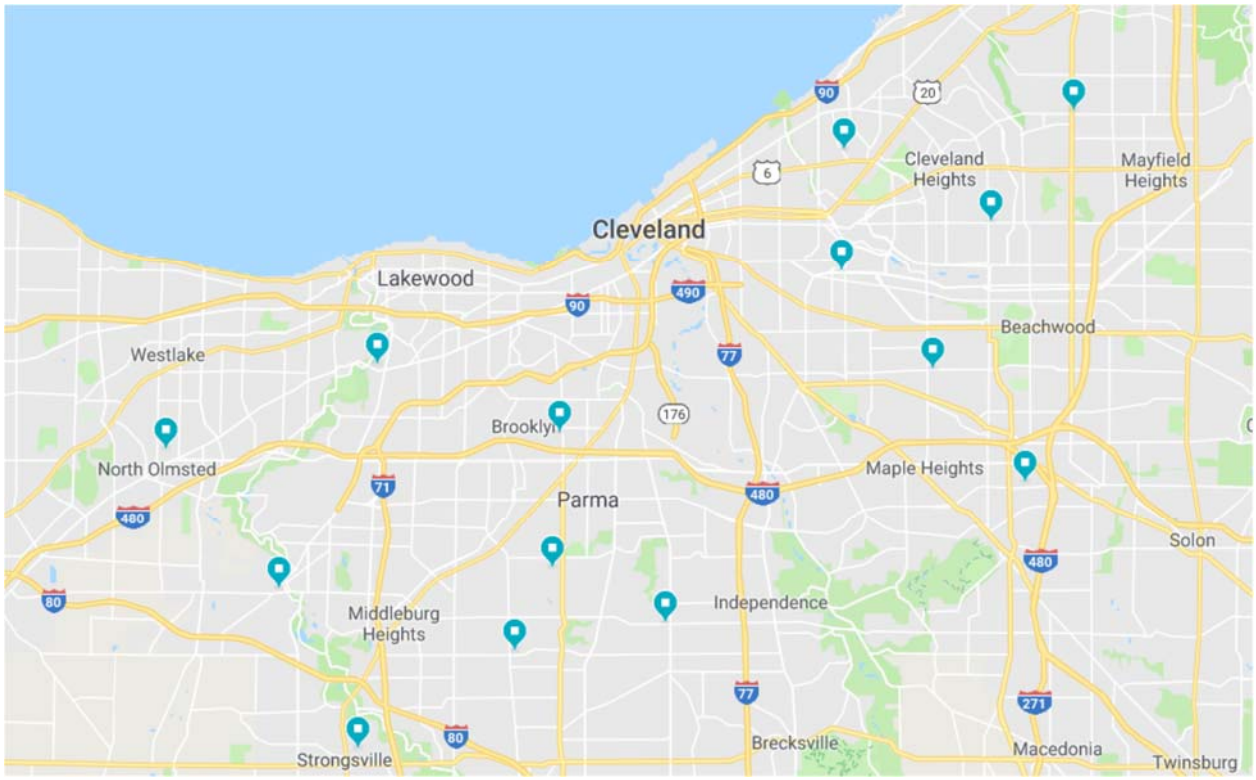
187. Dr. McCann's analysis combines these two stores' data and presents them as though they were one store, suggesting a volume increase at one store that never occurred. Not surprisingly, for all six of the store relocations identified in Appendix F of the Brunner Expert Report, all new store locations had larger volumes than the prior locations.[376] No due diligence is necessary to understand why new, improved store locations (e.g., store #12444) would have greater volume shipments as compared to the old store locations (e.g., #3309).

2. Tops Pharmacies Closed

188. In November 2006, Tops Markets announced the closure or sale of its 46 stores in northeast Ohio.[377] Of the 46 stores, which include pharmacies, 18 were sold to Giant Eagle, 4 sold to Dave's Supermarkets, 1 to be run by an independent Giant Eagle operator, and the remainder (28) would close on December 8, 2006 if not sold.[378]

189. I understand from Mr. Brunner that 22 of the 46 stores were located in Cuyahoga County.[379] Of these 22, 14 stores never re-opened in Cuyahoga County.[380] The map screen shot below identifies the Tops stores in Cuyahoga County that permanently closed in December 2006.[381]

[376] Expert Report of Robert L. Brunner, May 10, 2019, Appendix F.
[377] https://www.crainscleveland.com/article/20061109/FREE/61109008/tops-stores-to-close.
[378] https://www.crainscleveland.com/article/20061109/FREE/61109008/tops-stores-to-close.
[379] Conversation with Mr. Brunner.
[380] Conversation with Mr. Brunner.
[381] Conversation with Mr. Brunner.



Prescriptions that were filled at these Tops stores that closed permanently or temporarily during transition to new ownership likely would have been filled at other surrounding pharmacies, including Walgreens. Dr. McCann's analyses and Mr. Rafalski's opinions do not contemplate any such factors. Readily available public information would explain and justify volume increases for Walgreens retail pharmacies that were located near the former Tops stores – no written due diligence would be necessary.

3. Mr. Rafalski Fails to Consider the Importance of Drug Strengths

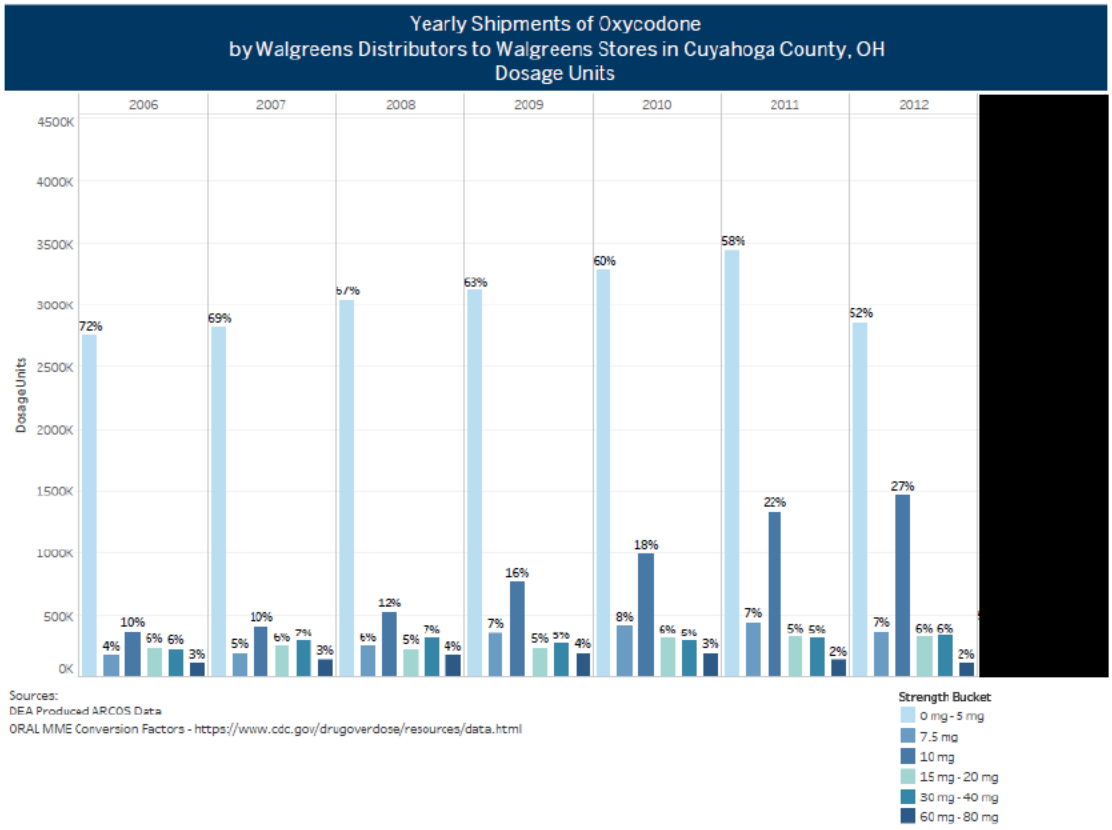
190. Analysis of drug strengths that are subject to greater abuse is often performed when evaluating suspicious orders or investigating diversion. Mr. Rafalski acknowledged that the there are certain drug strengths, such as oxycodone 30mg, that are more "*highly abused*."[382] However, Mr. Rafalski does not analyze any data that looks at shipments of various drug

[382] Deposition of James Rafalski, May 13, 2019, p. 64 and May 14, 2019, p. 720.

strengths in arriving at his opinions that Walgreens did not maintain effective controls against diversion.

191. The Brunner Report included charts that analyzed Walgreens' shipments of hydrocodone and oxycodone by drug strength for Cuyahoga and Summit Counties.[383] The chart below presents annual shipments of oxycodone 30mg by Walgreens Distribution Centers to Cuyahoga County:[384]

Figure 22 - Annual shipments of Oxycodone by Walgreens Distributors to Walgreens Stores in Cuyahoga County, by drug strength



[383] Expert Report of Robert L. Brunner, May 10, 2019, Appendix G.
[384] Expert Report of Robert L. Brunner, May 10, 2019, p. 47.

As clearly seen above, [redacted]

192. Again, Plaintiffs did not perform any such analyses in an attempt to identify suspicious orders or diversion.

E. Methodology Used to Flag Orders as Potentially Suspicious is Unsupported and Unreliable

193. Dr. McCann applies five different methodologies for "flagging" potentially suspicious orders. Upon an order triggering one of the five flagging methodologies, Dr. McCann and Mr. Rafalski characterized all transactions after that point as suspicious and concluded they should not have been shipped based on an assumption of no due diligence. Effectively, all orders placed after the first flagged order are assumed to be diverted. Mr. Rafalski relies on the results of this analysis to conclude that over [redacted]% of all orders shipped by Walgreens Distribution Centers to its retail pharmacies in Cuyahoga and Summit Counties were diverted into illicit channels and caused overdoses and deaths.

194. Dr. McCann's and Mr. Rafalski's methodology and assumptions used to flag orders as suspicious are fundamentally flawed. Reasons for this are discussed below.

1. Rafalski Asserts that Masters is the only suitable Methodology

195. Mr. Rafalski testified that he chose the five methodologies discussed in his report because, he asserted, they were used by one or more companies in his report during the timeframe of his report.[385] However, Mr. Rafalski also acknowledged that there could be other methods of identifying suspicious orders that registrants use in the real world.[386]

[385] Deposition of James Rafalski, May 13, 2019, pp. 163-164.
[386] Deposition of James Rafalski, May 14, 2019, pp. 483-484.

196. Of the five methodologies, Mr. Rafalski asserts that "*the test set forth in [Masters Pharmaceutical, Inc. v. Drug Enforcement Administration] provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size*."[387] Mr. Rafalski later testified that the *Mast*ers *Pharmaceutical* method is suitable as a "*trigger mechanism or threshold to establish that, an order as being potentially suspicious*"[388] because "*it has been reviewed and an order issued – or an opinion [was] issued by the D.C. court.*"[389] Mr. Rafalski lacks any basis to conclude that the methodology employed in the *Masters Pharmaceutical* case would be reasonable to apply to all Defendants over the entire time period. The *Masters Pharmaceutical* case called for a flagging methodology that was triggered when an order exceeded the maximum order over the last six months.

197. First, Mr. Rafalski's version of the Masters method is different from any method actually used in the real world, because he assumes, counterfactually, that no diligence is done on the first flagged order, so that all subsequent orders are flagged.

198. Second, the *Masters Pharmaceutical* decision was not issued until 2017.[390] By setting the Masters Pharmaceutical methodology as the end-all-be-all for flagging orders as potentially suspicious, Mr. Rafalski is playing Monday-morning-quarterback. In essence, Mr. Rafalski assumes that Walgreens, and all Defendants, should have known to apply this specific methodology to identify suspicious orders all the way back at the beginning of their suspicious order monitoring systems.

199. Third, the *Masters Pharmaceutical* case related to diversion resulting from sales to rogue internet pharmacies.[391] Walgreens Distribution Centers did not distribute any controlled substances to non-Walgreens retail pharmacies, let alone internet pharmacies. The applicability

[387] Rafalski Report, p. 46.
[388] Deposition of James Rafalski, May 14, 2019, p. 482.
[389] Deposition of James Rafalski, May 13, 2019, p. 176.
[390] *Masters Pharm., Inc. v. Drug Enf't Admin*, 861 F3.d 206, 216-17 (D.C. Cir. 2017).
[391] The *Southwood Pharmaceuticals* case also related to rogue internet pharmacies.

of this methodology to Walgreens Distribution Centers with a different business model is inappropriate and certainly not compelled by law.

200. Fourth, in the *Masters Pharmaceutical* case, actual diversion through poor dispensing practices at the rogue internet pharmacies were demonstrated. In other words, an investigation to establish diversion into illicit channels was actually performed; in this matter, Plaintiffs have not established that any orders filled by Walgreens Distribution Centers for Cuyahoga and Summit Counties were actually diverted.

201. Fifth, DEA did not approve or recommend methodologies for identifying suspicious orders, as confirmed by the testimony of Mr. Rannazzisi, Mr. Wright, Ms. Ashley, and Mr. Prevoznik.[392] In my experience at Amneal, the DEA did not approve or recommend methodologies for identifying suspicious orders. At the end of the day, DEA made clear that it was up to a business, based on its knowledge of its customers and its business model, to use its judgment when establishing a suspicious order monitoring system; i.e., there is no one size fits all. Although Mr. Rafalski even testifies himself that there may be other flagging criteria that would be appropriate to use, he still takes the position that *Masters Pharmaceutical* methodology is the only suitable method to apply to all Defendants, including Walgreens.

202. Sixth, Mr. Rafalski testified that he personally did not do any tests of the five methodologies' abilities to identify suspicious orders -- McCann did it.[393] Dr. McCann testified that he had no opinion regarding any of the five methodologies.[394] There is no basis to support why the *Masters Pharmaceutical* methodology or any other methodology is appropriately applied to Walgreens. Nor did Mr. Rafalski verify that Dr. McCann's results were accurate, or even whether they reflected what Mr. Rafalski had asked Plaintiffs' counsel to ask Dr. McCann to do:[395]

[392] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 43, 317-318, 321; Deposition of Kyle Wright, February 28, 2019, p. 196; Deposition of Demetra Ashley, March 15, 2019, pp. 88-89; Deposition of Thomas Prevoznik, April 18, 2019, p. 446.
[393] Deposition of James Rafalski, May 14, 2019, pp. 471-472.
[394] Deposition of Craig McCann, May 9, 2019, p. 269.
[395] Deposition of James Rafalski, May 14, 2019, p. 507.

Q. You can't vouch for the accuracy of any of the numbers that appear in these tables at pages 41 to 45 of your report, correct, sir?
A. Mr. McCann would have to testify to the accuracy. He did the analysis.
Q. You just relied on what Mr. McCann provided, correct, sir?
A. Yes, I did.

203. Finally, given Mr. Rafalski testifies that there may be other flagging methodologies that would be appropriate, this could include the other methodologies applied by Dr. McCann. A summary of the Walgreens percentages of flagged orders based on the five flagging methodologies applied by Dr. McCann as reported in the Rafalski Report is below:[396]

Five Flagging Methodologies Used by Dr. McCann	Cuyahoga County 1996 - 2018				Summit County 1996 - 2018			
	Flagged Orders of Oxycodone (Dosage Units)	*% of Total Units*	Flagged Orders of Hydrocodone (Dosage Units)	*% of Total Units*	Flagged Orders of Oxycodone (Dosage Units)	*% of Total Units*	Flagged Orders of Hydrocodone (Dosage Units)	*% of Total Units*
Maximum Monthly - Trailing 6 Month Threshold	REDACTED							
2x Trailing 12 Month Average								
Extraordinary Order Method – 3x Trailing 12 Month Average								
Maximum 8,000 Dosage Units Monthly								
Maximum Daily Dosage Units								
Total Dosage Units								

If any of these methodologies could be appropriate (as well as others not identified here, including what Walgreens was actually doing), Mr. Rafalski has no basis to select the Masters

[396] Rafalski Report, pp. 41-46.

method over any other method for identifying suspicious orders. For example, setting aside Mr. Rafalski's assumption that every order is flagged after the first triggering transaction, his "Extraordinary Order Method – 3x Trailing 12 Month Average" shares some features of the reporting methods Walgreens used until 2012. Such reporting methods were approved by DEA for decades. And even when excessive purchase reporting based on methods such as a "3x trailing 12 month average" fell out of favor with the DEA, it was because they identified ***too many*** orders as potentially suspicious and failed to winnow down the reports to what was truly suspicious.[397] Yet Mr. Rafalski opines that the ***only*** suitable method of flagging suspicious orders is one that identifies [redacted] of Walgreens orders suspicious. This flies in the face of all DEA guidance and is contrary to law.

2. First Flag Results in Flagging of all Subsequent Orders

204. Under Dr. McCann's analysis, after a Walgreens order is flagged using the *Masters Pharmaceutical* methodology (or any of the other four flagging methodologies), every subsequent order is also flagged. Per Mr. Rafalski, these subsequent orders should not have been shipped until the first potentially suspicious order had been 1) resolved as not suspicious through due diligence or 2) reported to the DEA as suspicious because due diligence did not resolve outstanding suspicions. Mr. Rafalski testified:[398]

> *"So the methodologies applied to the distribution, once the suspicious order is identified, the criteria I used is if there was no due diligence to dispel the suspicious order or it wasn't reported, then every subsequent distribution would be a suspicious order."*

205. Mr. Rafalski further testified that a critical assumption in support of flagging all subsequent orders was based on due diligence:[399]

[397] Deposition of Kyle Wright, February 28, 2019, pp. 83-86.
[398] Deposition of James Rafalski, May 13, 2019, p. 166.
[399] Deposition of James Rafalski, May 13, 2019, p. 183.

> *"Q: So your entire analysis here rests on the premise that no due diligence was done on the orders that you're reporting on here; is that right?*
>
> *A: No – either no or insufficient due diligence."*

In other words, if Mr. Rafalski's assumption that "*no or insufficient*" due diligence was performed on flagged orders is wrong, the flagging of all subsequent orders is speculative and wholly unsupported.[400] Moreover, there were no applications of the five flagging methodologies performed on subsequent orders.[401]

206. Mr. Rafalski acknowledges in testimony that there is subjectivity related to steps taken after an order is flagged using the automated criteria: "*[t]he actual identification*" of a suspicious order would not be subjective because "*a large company has sufficient data that they can come up with a reasonable, usual amount that a customer would be expected to purchase, and I think that a purchase that would exceed that as a system that would trigger that order to be of unusual size…;*"[402] however, "*[s]ubsequent decision may be subjective, but the actual identification would not be.*"[403] The subsequent decision (referenced above) would relate to 1) whether the due diligence resolved the potentially suspicious aspects of the order and 2) whether the order should be shipped.

207. Even more problematic, Mr. Rafalski's opinion is premised on orders of an unusual size or frequency or orders that deviate from a pattern, but Mr. Rafalski never looked at any orders. Mr. Rafalski testified that he did not examine any actual orders to reach any such conclusion:[404]

[400] As discussed in Section IX.D, Walgreens did have policies and procedures in place to conduct due diligence.
[401] Deposition of Craig McCann, May 9, 2019, p. 271.
[402] Deposition of James Rafalski, May 13, 2019, pp. 60-61.
[403] Deposition of James Rafalski, May 13, 2019, pp. 60-61.
[404] Deposition of James Rafalski, May 13, 2019, pp. 197–198.

> *Q: I want to understand whether your analysis involved review of specific particular orders on particular days, sent to particular – sent by particular pharmacies to distributors.*
>
> *A: My analysis to form this opinion wasn't specific to looking at each order by order.*

208. Mr. Rafalski testified that he "*didn't go to Dr. McCann's report and look at any order of – that flagged on any of the analyses*."[405] In fact, Mr. Rafalski testified that he had not even read Dr. McCann's report before he put together the section of his report that contains summary tables of flagged orders by county, by defendant, and by flagging methodology.[406]

209. Mr. Rafalski even testified that he did not need to identify any orders that were suspicious to perform his assignment and reach his conclusion: "[*I*]*n my assignment to create this and do the investigation to come to this opinion, there wasn't a requirement for me to actually find specific orders that were suspicious*."[407] Mr. Rafalski did not task himself to do that:[408]

> *Q: So sitting here today, you can't identify a particular order from a particular pharmacy that should have been reported as suspicious that wasn't; is that correct?*
>
> *A: I don't know because I didn't task myself to do that.*

210. I do not know how Mr. Rafalski can draw any conclusion that Walgreens had suspicious orders without examining any orders. I have reviewed the appendices to Mr. Brunner's report (in particular Appendix C, D,[409] and Appendix H), which provide a store-by-

[405] Deposition of James Rafalski, May 14, 2019, p. 489.
[406] Deposition of James Rafalski, May 14, 2019, p. 473.
[407] Deposition of James Rafalski, May 13, 2019, p. 192.
[408] Deposition of James Rafalski, May 13, 2019, p. 193.
[409] Appendix D to the Brunner Report charts 20 allegedly suspicious orders identified by Plaintiffs. I located nine of those orders in the Suspicious Control Drug Order reports (based on Appendix E-3) that Walgreens sent to DEA.

store analysis of shipped orders that is missing from Dr. McCann's report. Mr. Brunner's charts confirm that there is nothing suspicious or unusual in the volumes that Walgreens shipped to its pharmacies in Summit and Cuyahoga Counties.

3. Non-sensical Results

211. Despite Mr. Rafalski's inability to report any flagged order leading to diversion, it is Mr. Rafalski's opinion that over [redacted] of the oxycodone and hydrocodone orders that were shipped by Walgreens Distribution Centers to Cuyahoga and Summit Counties were diverted.[410]

- % of Total Dosage Units of Hydrocodone Flagged for Cuyahoga: [redacted]
- % of Total Dosage Units of Oxycodone Flagged for Cuyahoga: [redacted]
- % of Total Dosage Units of Hydrocodone Flagged for Summit: [redacted]
- % of Total Dosage Units of Oxycodone Flagged for Summit: [redacted]

Mr. Rafalski testified that he did not do any analysis of how many people would not have gotten their medication or how many legitimate prescriptions would have gone unfilled if 95% of Walgreens orders had not shipped.[411]

212. There is evidence from the DEA that very few, if any, of the prescriptions filled by the Walgreens retail pharmacies would be expected to be illegitimate. I have seen no evidence of ***any*** illegitimate prescriptions filled by Walgreens. The DEA has acknowledged on multiple occasions that there are very few over-prescribing practitioners. In 2006, written statements by Mr. Rannazzisi stated that less than .01% of all physicians were over-prescribing.[412] In 2014,

---

For Cuyahoga County: #1 at WAGMDL00395713 – 714; #2 at WAGMDL00395729 - 730; #5 at WAGMDL00394459 – 460; #6 at WAGMDL00395124 – 125; and #7 at WAGMDL00390757 – 758. For Summit County: #5 at WAGMDL00395745 – 746; #6 at WAGMDL00393581 – 582; #8 at WAGMDL00395106 – 107; and #10 at WAGMDL00393114 – 115.

[410] Rafalski Report, pp. 41-46.

[411] Deposition of James Rafalski, May 14, 2019, p. 476.

[412] Deposition of Joseph Rannazzisi, April 26, 2019, Exhibit 7 at p. 10 (Rannazzisi Statement Before Congress – July 2012).

Mr. Rannazzisi testified to Congress that 99.5% of prescribers were not overprescribing.[413] In 2018, acting administrator of the DEA testified that 99.99% of prescribers were "trying to do right by their patients."[414] If most practitioners are prescribing for legitimate medical reasons as stated by the DEA, then Mr. Rafalski's conclusion that over 95% of Walgreens dosage units of hydrocodone and oxycodone makes no sense.

F. Mr. Rafalski Retroactively Applies Guidance from an Undisclosed Source

213. Mr. Rafalski testified that all components listed in pages 37-40 of the Rafalski Report are required under 1301.74(b), but also thinks it would be *"possible to have a compliant suspicious order monitoring system without all [the] components"* listed on pages 37-40 of his report.[415]

214. To comply with the law, Mr. Rafalski also testified that "*a distributor has to perform all of the due diligence steps located on p. 39 of his report*."[416] However, Mr. Rafalski also admits that "*[i]t's up to the registrant to design a system that makes sense for that registrant's business*."[417]

215. I am unaware of any support for that opinion anywhere. The list of components of a suspicious order monitoring system and due diligence program that appears at pages 37-40 of Mr. Rafalski's report does not appear in the CSA. It does not appear in § 1301.74(b) or any other DEA regulation. It does not appear in the Suspicious Orders Task Force Report, the Chemical Handler's Manual, or Mr. Rannazzisi's "Dear Registrant" letters from 2006 and 2007. Mr. Rafalski testified that his methods for assessing the Defendants' suspicious order monitoring systems were based in part on his experience, training, and guidance from lawyers at DEA, but he refused to disclose any of the legal guidance that supported his opinions.[418] I am forced to conclude that Mr. Rafalski has based his list of required components at pages 37-40 of his report

[413] Deposition of Joseph Rannazzisi, April 26, 2019, p. 192.
[414] Deposition of Thomas Prevoznik, April 18, 2019, Exhibit 15 at p. 32.
[415] Deposition of James Rafalski, May 14, 2019, pp. 447-448.
[416] Deposition of James Rafalski, May 14, 2019, p. 449.
[417] Deposition of James Rafalski, May 14, 2019, p. 484.
[418] Deposition of James Rafalski, May 14, 2019, p. 842.

on this undisclosed guidance. But I do not understand how Mr. Rafalski can assert that these components are all required by law when the DEA was not providing guidance on what a compliant suspicious order monitoring system should be. Moreover, I disagree with Mr. Rafalski that the long list of requirements he includes in his report is, in fact, required by any law or regulation.

G. Dr. McCann's Excessive Shipments Analysis is not Reliable

216. Dr. McCann's includes in his report an analysis where he purports to identify the amount of per capita opioid MME that was in excess of what was medically necessary to support his identification of transactions.[419] In arriving at the amount of per capita opioid MME that exceeded medically necessary amounts, Dr. McCann must "assume" the level of medically necessary per capita opioid MME.[420] His two "assumed" baselines are based on the following:[421]

- Lower bound: assumes all prescriptions of opioids in 1997 were necessary and all opioid use per capita beyond 1997 levels were unnecessary.
- Upper bound: assumes that 1997 and 2018 per capita opioid MME is medically necessary. He draws a line between the 1997 and 2018 values for per capital opioid MME. Any per capita opioid MME amounts that exceed the 1997-2018 line were unnecessary.

Dr. McCann does not provide any basis for his assumption that 1997 represents medically necessary opioid prescriptions to use that value as his starting point. As a result, this analysis is unreliable and not relevant.

[419] McCann Report, p. 88.
[420] McCann Report, p. 84.
[421] McCann Report, p. 84.

H. DEA Had Full Knowledge of the Increasing Volume of Prescription Opioids

217. Not only did Mr. Rafalski fail to establish that Walgreens had suspicious orders that were diverted to cause the opioid epidemic, he also overlooks that the DEA knew that the volumes of Prescription Opioids were increasing and that there was an epidemic. Furthermore, at the same time that the DEA knew that the prescription opioid epidemic was occurring, the DEA increased the annual quotas of raw material used to manufacture Prescription Opioids.

218. Through the reporting requirements of both manufacturers and distributors, the DEA and other law enforcement organizations/agencies had ARCOS data. The ARCOS data contains the total movements of all controlled substances. The ARCOS data can be used to analyze, investigate, and monitor types of controlled substances, quantities and strengths thereof, differences by regions, shipments to specific pharmacies/clinics/hospitals, and any number of other mechanisms to detect and reduce the abuse of controlled substances.[422] Such information would include the movements of all Prescription Opioids in Cuyahoga and Summit Counties.

219. The DEA had ARCOS data over the entire period. Despite having such data, the DEA's use of the ARCOS data to detect diversion was limited from 2006 through 2015. For example, DEA did not institute any procedures requiring field divisions to establish an ARCOS review committee to analyze any ARCOS leads/information received from DEA headquarters to assess how that information from ARCOS could identify where diversion was occurring in the district.[423] In addition, each division field office differed in follow-up on investigative leads.[424] There were not policies in place during 2006 to 2015 that tracked use of ARCOS data in generating investigation leads.[425] Moreover, the DEA had no policy in place from 2006 through 2015 to investigate every suspicious order report that was received by DEA,[426] nor was there any central body anywhere within the DEA organized to review suspicious order reports.[427] Every

[422] https://www.deadiversion.usdoj.gov/arcos/handbook/section1.htm.
[423] Deposition of Thomas Prevoznik, April 18, 2019, p. 520.
[424] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 156-159.
[425] Deposition of Thomas Prevoznik, April 18, 2019, pp. 511-513, 520-521.
[426] Deposition of Thomas Prevoznik, April 18, 2019, pp. 558, 566.
[427] Deposition of Thomas Prevoznik, April 18, 2019, pp. 564-565.

DEA Field Office has diversion groups and tactical diversion groups with assigned areas of responsibility that could have engaged in such review.[428] Unlike the DEA and other law enforcement agencies, Walgreens and the other Defendants did not have ARCOS data for other distributors' shipments to specific counties or to specific pharmacies.[429]

220. In addition to ARCOS data, the DEA also had access to IMS data. While working at Amneal, DEA personnel stated to me that the DEA had access to IMS data that had information on controlled substances that could be used to track the sales of all reportable controlled substance products U.S. It can also be used to evaluate trends to identify diversion investigations.[430] Also, the DEA encouraged the use of other anti-diversion tactics focused on prescribers such as PDMPs. In April 2011, the Office of National Drug Control Policy ("ONDCP") released a new strategy that included "*work[ing] with states to establish effective PDMPs*."[431] PDMPs, or Prescription Drug Monitoring Programs, are electronic databases maintained by states that track controlled substance prescriptions in a state. "*One of the best ways to combat the rising tide of prescription abuse is the Prescription Drug Monitoring Programs (PDMP). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists*."[432]

221. Moreover, the DEA could also utilize state and local law enforcement to investigate diversion leads.

222. The DEA's ODC sets annual Aggregate Production Quotas ("APQs") for Schedule I and II controlled substances and certain List 1 chemicals.[433] These APQs determine the annual

[428] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 150-153.
[429] Deposition of Joseph Rannazzisi, April 26, 2019, p. 25.
[430] Deposition of Joseph Rannazzisi, April 26, 2019, pp. 29-30, 178-179.
[431] Deposition of Edward Bratton, November 30, 2018, Exhibit 5 at WAGMDL00289090 (Drug Trends Presentation – December 2012).
[432] Drug Enforcement Administration Congressional Budget Submission for Fiscal Year 2011, p. 18.
[433] Deposition of Joseph Rannazzisi, April 26, 2019, p. 30; https://www.deadiversion.usdoj.gov/quotas/quota_apps.htm.

quantities of controlled substances and List 1 chemicals available for national medical, scientific research, and industrial needs of the U.S. over the coming year.[434] Each year's quota is set individually[435] and considers the following factors: manufacturers' quota applications, changes in marketplace, manufacturers' changes to their processes, export requirements, inventory allowances, new indications or removal of indications, or other changes in FDA approval.[436, 437] In setting the quotas, DEA would also consider "*known quantifiable seizure data…from state and local law enforcement agencies or labs.*"[438] I am unaware of any evidence that indicates that Walgreens provided input into annual APQs.

223. Given that the DEA approved annual APQs, the DEA could have reduced the annual APQs in an effort to reduce the available volume of raw materials used to manufacture hydrocodone and oxycodone if the DEA believed that there was widespread diversion due to excess amounts of product. In an opinion piece published by the Washington Post in December 2017, a Former Associate Chief Counsel for the DEA's Diversion and Regulatory Litigation Section indicated the DEA had taken such action before:[439]

> *"In the 1970s, the DEA significantly reduced the amphetamine quota to successfully combat rising abuse of speed pills. In the 1980s, the methaqualone quota was reduced to combat the illicit use of quaaludes. It is perplexing why the DEA did not address the opioid epidemic in the same manner."*

Specific to Prescription Opioids, leaders of DEA have suggested using APQ reductions for compliance or enforcement purposes. In 2001, the DEA Administrator at the time Donnie

[434] Deposition of Joseph Rannazzisi, April 26, 2019, p. 30; https://www.deadiversion.usdoj.gov/quotas/quota_apps.htm. Annual quotas are provided in the aggregate and also to individual registrants (Deposition of Joseph Rannazzisi, April 26, 2019, p. 95).
[435] Deposition of Stacy Harper-Avilla, April 11, 2019, pp. 30-31.
[436] Deposition of Stacy Harper-Avilla, April 11, 2019, p. 42.
[437] Deposition of Joseph Rannazzisi, April 26, 2019, p. 94.
[438] Deposition of Stacy Harper-Avilla, April 11, 2019, pp. 73-74.
[439] https://www.washingtonpost.com/opinions/the-real-history-of-the-dea-and-opioids/2017/12/01/6ab9d194-d5f7-11e7-9ad9-ca0619edfa05_story.html?utm_term=.5366af41f6ca; https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-opioid-epidemic-factsheet.pdf.

Marshall publicly testified that he considered controlling the supply of Oxycontin by "*rolling back*" the quotas the DEA sets to 1996 levels.[440]

224. Mr. Rannazzisi testified that the APQs for hydrocodone and oxycodone increased under his leadership from 2005 to 2015.[441] Ms. Harper-Avilla has worked with APQs for the DEA since 2008.[442] She testified that the APQs in the years where she approved them were based on legitimate U.S. needs:[443]

> Q. During any year in which you approved those numbers, did you feel that they did not reflect the legitimate medical, scientific and industrial needs of the United States?
>
> MR. CHANDLER: Objection. Scope.
>
> THE WITNESS: No.

The table below identifies the APQs for hydrocodone and oxycodone for the years 2005, 2010, and 2015.[444]

	2005	2010	2015
Hydrocodone	37,604.000	55,000.000	99,625.000
Oxycodone (sale)	50,490.000	105,500.000	137,500.000

For hydrocodone, the APQ in 2005 was 37,604; in 2015, it was 99,625. For oxycodone, the APQ in 2005 was 50,490; in 2015, it was 137,500.

[440] https://www nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html; https://www.thedailybeast.com/dea-secretly-oks-killer-quantities-of-oxy-and-morphine.
[441] Deposition of Joseph Rannazzisi, April 26, 2019, p. 31.
[442] Deposition of Stacy Harper-Avilla, April 11, 2019, p. 23.
[443] Deposition of Stacy Harper-Avilla, April 11, 2019, p. 82.
[444] Deposition of Joseph Rannazzisi, April 26, 2019, Exhibit 2 (APQ History for Selected Substances – 2005-2015).

225. The DEA approved quotas for the manufacture of prescription opioids based on estimated, legitimate needs for the drugs. If the quotas were increasing based on legitimate medical, scientific, and industrial U.S. needs, then there would also be increasing supply and distribution of prescription opioids. Again, Mr. Rafalski's opinion that diversion occurred because the volume of prescription opioid shipments increased fails to actually establish that any diversion actually occurred. If APQs are increased for legitimate reasons, then the volumes of legitimate orders for prescription opioids would also be expected to increase. Furthermore, the role of a Suspicious Order Monitoring System is to identify diversion – not general changes in prescribing behavior over time.

226. The DEA played a central role in all aspects of the supply of prescription opioids: the DEA sets the APQs, the DEA regulates the manufactures, the DEA regulates the distributors, the DEA regulates the pharmacies, and the DEA regulates the practitioners.

227. In conclusion, Mr. Rafalski's failure to consider DEA's central role in the regulation and supply of prescription opioids ignores a critical factor leading to the volume of opioids that moved through the closed system of distribution in the relevant timeframe. Mr. Rafalski's failure to consider this, among other factors, further undercuts his conclusions.

****

Signed by: Gregory Anderson

Appendix A

Gregory Anderson
Consultant
DEA Compliance | Pharmaceutical Drug Diversion | Law Enforcement |Security (Physical, Personnel, Intellectual Property)
granderson517@outlook.com | 571-309-7154

SUMMARY

Technical Advisor that is a retired government and pharmaceutical industry executive drawing on 28 years of experience as a Special Agent/Criminal Investigator with the United States Drug Enforcement Administration (DEA) and six years within the pharmaceutical industry as a Vice President of DEA Compliance and Corporate Security. I administrated the controlled substance compliance program, ensuring complete compliance according to the Controlled Substances Act (CSA) and Code of Federal Regulations (CFR).

During my 28 years with DEA, 12 years included management/executive positions. The last two years of my career with DEA, I was assigned to the Office of Diversion Control at DEA Headquarters whose mission is to prevent diversion and enforce the Controlled Substances Act (CSA).

EDUCATION

- Bachelor of Science in Criminal Justice, Kentucky State University: May 1980
  Dean's List, 1978 – 1979
  Student Government, Chief Justice Student Court, 1978 – 1979
- Certification, Strategic Thinking, Johns Hopkins Executive Leadership Institute: November 2008.
- Certification, Executive Leadership, University of Virginia Executive Leadership Institute: June 2010.

PRVIATE EXPERIENCE

Vice President of DEA Compliance and Corporate Security; Amneal Pharmaceuticals
Long Island, New York; April 2012 to July 2018

As the Vice President, my duties and objectives were to improve the controlled substances compliance program and the corporate security procedures. The first two procedures I established were the development of a cohesive risk management team and the development of an active, real-time internal security program. In addition, I established continuity by updating the compliance/security protocols for procuring, handling and storing controlled substances. I updated the SOMP policies and procedures. I implemented new conduct standards (SOPs). I ensured compliance procedures and guidelines conformed with Corporate and State regulations. I ensured they complied under the Controlled Substances Act (CSA), and both governmental regulating agencies: United States Food and Drug Administration and United States Drug Enforcement Administration. With my experience and background, I designed and established a 24-hour Global Security Operations Center (GSOC). The GSOC integrated all New York and New Jersey facilities with closed circuit television (CCTV), alarms (intrusion, burglary and fire) and access control. This allowed the GSOC to monitor over 800

cameras, all burglary/fire alarms, emergency (smoke & water) sensors and 1000+ doors. The GSOC resulted in a successful security countermeasure. GSOC enhanced accountability of controlled substances materials, high-value non-control materials and intellectual property. In addition, I established tracking procedures combined with real-time communications and CCTV; this minimized risk for random acts of pilfering and displayed prevention.

GOVERNMENT EXPERIENCE

I have over 28 years of experience with the United States Drug Enforcement Administration, of which, 13 years were management/executive positions. Seven years of my management/executive positions were served at DEA Headquarters: I served two years as the Section Chief (SC) in the Office of Diversion Control, ODS; three years in Operations Management, Organized Crime Drug Enforcement Task Force (OCDETF); and two years as a Staff Coordinator, Operations Management, Europe, Asia, Africa and Canada section.

Section Chief (GS-15): Office of Diversion Control, Synthetics and Chemical Section (ODS); **Arlington, Virginia; 2010 to 2012.** As the Section Chief for ODS, my duties and responsibilities included: coordinating, funding, initiating (national and international) synthetic operations. In addition, I administered the List I chemicals operations and clandestine lab certifications of lab equipment for the DEA Clan lab teams in the 32 DEA field divisions. The main goal of the SC is overseeing operations that support and ensure Agents, Investigators and State & Local Officers are consolidating their assets and sharing information that would result in successful prosecution. My duties also included financial and strategic support. Communications with private sector in chemical- and precursor-related compliance matters (i.e., reviews for importation of List I chemicals, Letters of No Objections) and chemical registrant submissions background investigations. SC Anderson's section supported chemicals and precursor chemical movements worldwide. I briefed Senior Executive Service (SES) management on all progress, significant developments and problems involving chemicals, synthetic compounds, safety, injuries and related Field Division matters. During my time with ODS, I achieved the highest performance rating of Outstanding every year, with two Superior Achievement awards.

Section Chief (GS-15): Organized Crime Drug Enforcement Task Force (OCDETF) Section; **Arlington, Virginia; 2007 to 2010.** As the Section Chief for the Office of Management OCDETF section (OMO), my duties and responsibilities were managing and overseeing OCDETF's $16M budget for illicit drugs related to organized crime investigations. My staff serviced all 32 field divisions within DEA. I worked jointly with the Department of Justice (DOJ), the Washington Area Regional Group (WARG), the Federal Bureau of Investigations (FBI), Immigrations Custom Enforcement (ICE), Custom Border Patrol (CBP), Internal Revenue Service (IRS), United States Marshal Service (USMS), and United States Coast Guard (USCG). OCDETF is the nation's oldest and premier task force. During my time with OCDETF (three years), I achieved the highest performance rating of Outstanding every year.

Staff Coordinator (GS-14): Europe, Asia, Africa and Canada Section (OGE); Arlington, Virginia; 2005 to 2007. As a Staff Coordinator in Global Enforcement Operations (OGS), my duties included assisting and supporting the DEA country offices assigned. I provided services for operational funding, travel authorizations and international controlled deliveries. I was the

point of contact for all significant reporting between DEA Headquarters and the Foreign offices assigned. The country offices I was assigned to were in Europe, Africa, Asia and Canada (15 total).

Supervisory Special Agent (GS-14): High Intensity Drug Trafficking Areas (HIDTA), Clandestine Divisional Lab Group and the Homicide Task Force (Redrum); Detroit, Michigan; 1999 to 2005. I served as the Group Supervisor for three different enforcement groups: 1.) High Intensity Drug Enforcement Task Force (HIDTA); 2.) Drug related homicide task force (Redrum); and 3.) Divisional Clandestine Laboratory (Clan Lab) response and training group. Each group consisted of DEA Special Agents, Detroit Homicide Detectives, Michigan State Police Detectives and multiple State and Local Task Force Officers from the Departments of Dearborn, Southfield, Redford Township, Highland Park, Inkster and Wayne County Sheriffs. Our mission and objectives were to enforce and support illegal drug related crimes and acts that violated Federal and State drug laws. I led men and women in high risk drugs, homicides and clandestine manufacturing/illicit chemical investigations. My leadership resulted in multiple arrests and successful prosecutions in both Federal and State courts.

Special Agent (GS-13): United States Department of Justice, Drug Enforcement Administration; United States Embassy, Islamabad, Pakistan; Lahore, Pakistan Consulate; 1997 to 1999. My duties and responsibilities were to maintain the Diplomatic Mission for the Security and Interest of the United States. Duties included being a member of the Country Team, act as liaison and subject matter expert for Host Country counterparts, other expatriate counterparts and Government Agencies.

Special Agent (GS-7 to GS-13): United States Department of Justice, Drug Enforcement Administration; Detroit, Michigan; 1984 to 2012. Duties and responsibilities were to enforce Federal and State drug trafficking laws under the Controlled Substances Act.

Other duties assigned:

- DEA Certified Instructor/Trainer
- DEA Field Trainer
- DEA Certified Clandestine Laboratory Investigator
- Assets Forfeiture Financial Investigator

AWARDS

DEA Administrator's Award
DEA Exceptional Performance
DEA Sustained Superior Performance
DOJ OCDETF Regional Case of the Year

PROFESSIONAL MEMBERSHIPS

Kappa Alpha Psi Fraternity, Inc.
Alpha Upsilon Foundation
Former President National Association Black Narcotics Agents

Appendix B

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
ABDCMDL00170319	ABDCMDL00170319
ABDCMDL00269683	ABDCMDL00269684
ABDCMDL00269685	ABDCMDL00269686
ABDCMDL00269687	ABDCMDL00269690
ABDCMDL00269691	ABDCMDL00269694
Acquired_Actavis_00441354	Acquired_Actavis_00441354
AKRON_000367619	AKRON_000367619
AKRON_001158027	AKRON_001158028
AKRON_001225698	AKRON_001225702
AKRON_001227427	AKRON_001227430
ALLERGAN_MDL_03755273	ALLERGAN_MDL_03755424
Anda_Opioids_MDL_0000646719	Anda_Opioids_MDL_0000646720
CAH_MDL_PRIORPROD_DEA07_00092296-R	CAH_MDL_PRIORPROD_DEA07_00092297-R
CAH_MDL_PRIORPROD_DEA07_00837645-R	CAH_MDL_PRIORPROD_DEA07_00837648-R
CAH_MDL_PRIORPROD_DEA07_01176247-R	CAH_MDL_PRIORPROD_DEA07_01176558-R
CAH_MDL_PRIORPROD_DEA07_01176914-R	CAH_MDL_PRIORPROD_DEA07_01177162-R
CAH_MDL_PRIORPROD_DEA07_01185382-R	CAH_MDL_PRIORPROD_DEA07_01185426-R
CAH_MDL_PRIORPROD_DEA12_00011059	CAH_MDL_PRIORPROD_DEA12_00011063
CAH_MDL_PRIORPROD_HOUSE_0002207	CAH_MDL_PRIORPROD_HOUSE_0002298
CAH_MDL2804_00953317	CAH_MDL2804_00953703
CAH_MDL2804_01431074	CAH_MDL2804_01431080
CAH_MDL2804_01483146	CAH_MDL2804_01483530
CAH_MDL2804_01563592	CAH_MDL2804_01563980
CAH_MDL2804_02203353	CAH_MDL2804_02203357
CAH_PRIORPROD_DEA12_00000609	CAH_PRIORPROD_DEA12_00000610
CAH_PRIORPROD_HOUSE_0002207	CAH_PRIORPROD_HOUSE_0002298
CUYAH_007488966	CUYAH_007488979
CUYAH_014632776	CUYAH_014632785
DOJ 0015336	DOJ 0015337
DOJ 0017101	DOJ 0017102
DOJ 037077	DOJ 037087
HDS_MDL_00002032	HDS_MDL_00002045
MCK-HOI-002-0000001	MCK-HOI-002-0000007
MCKMDL00330924	MCKMDL00330964
MCKMDL00337303	MCKMDL00337308
MCKMDL00478906	MCKMDL00478909
MCKMDL00478910	MCKMDL00478911
MNK-T1_0001454856	MNK-T1_0001454856

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
MNK-T1_0005986422	MNK-T1_0005986422
SUMMIT_000409493	SUMMIT_000409493
SUMMIT_000445937	SUMMIT_000445937
SUMMIT_001520592	SUMMIT_001520596
US-DEA-00000144	US-DEA-00000146
US-DEA-00000147	US-DEA-00000164
US-DEA-00000352	US-DEA-00000366
US-DEA-00000369	US-DEA-00000370
US-DEA-00000371	US-DEA-00000373
US-DEA-00025683	US-DEA-00025683
WAGFLDEA00000007	WAGFLDEA00000009
WAGFLDEA00000027	WAGFLDEA00000028
WAGFLDEA00000108	WAGFLDEA00000109
WAGFLDEA00000117	WAGFLDEA00000117
WAGFLDEA00000127	WAGFLDEA00000130
WAGFLDEA00000206	WAGFLDEA00000207
WAGFLDEA00000347	WAGFLDEA00000347
WAGFLDEA00000401	WAGFLDEA00000401
WAGFLDEA00000443	WAGFLDEA00000443
WAGFLDEA00000459	WAGFLDEA00000460
WAGFLDEA00000471	WAGFLDEA00000475
WAGFLDEA00000696	WAGFLDEA00000700
WAGFLDEA00000714	WAGFLDEA00000715
WAGFLDEA00000716	WAGFLDEA00000720
WAGFLDEA00000724	WAGFLDEA00000726
WAGFLDEA00000741	WAGFLDEA00000762
WAGFLDEA00000763	WAGFLDEA00000765
WAGFLDEA00000829	WAGFLDEA00000832
WAGFLDEA00000833	WAGFLDEA00000841
WAGFLDEA00000846	WAGFLDEA00000851
WAGFLDEA00000852	WAGFLDEA00000862
WAGFLDEA00000863	WAGFLDEA00000864
WAGFLDEA00000872	WAGFLDEA00000884
WAGFLDEA00000885	WAGFLDEA00000886
WAGFLDEA00000887	WAGFLDEA00000889
WAGFLDEA00000890	WAGFLDEA00000890
WAGFLDEA00000891	WAGFLDEA00000901
WAGFLDEA00000999	WAGFLDEA00001006

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGFLDEA00001087	WAGFLDEA00001093
WAGFLDEA00001141	WAGFLDEA00001144
WAGFLDEA00001160	WAGFLDEA00001160
WAGFLDEA00001288	WAGFLDEA00001327
WAGFLDEA00001348	WAGFLDEA00001348
WAGFLDEA00001498	WAGFLDEA00001505
WAGFLDEA00001511	WAGFLDEA00001513
WAGFLDEA00001518	WAGFLDEA00001523
WAGFLDEA00001746	WAGFLDEA00001746
WAGFLDEA00001747	WAGFLDEA00001766
WAGFLDEA00001776	WAGFLDEA00001853
WAGFLDEA00001854	WAGFLDEA00001855
WAGMDL00000360	WAGMDL00000360
WAGMDL00001233	WAGMDL00001233
WAGMDL00001234	WAGMDL00001236
WAGMDL00002896	WAGMDL00002897
WAGMDL00005359	WAGMDL00005365
WAGMDL00005366	WAGMDL00005366
WAGMDL00005369	WAGMDL00005373
WAGMDL00005577	WAGMDL00005577
WAGMDL00006645	WAGMDL00006646
WAGMDL00006890	WAGMDL00006896
WAGMDL00007981	WAGMDL00007986
WAGMDL00008078	WAGMDL00008084
WAGMDL00008085	WAGMDL00008092
WAGMDL00008093	WAGMDL00008099
WAGMDL00008100	WAGMDL00008101
WAGMDL00008102	WAGMDL00008103
WAGMDL00008104	WAGMDL00008105
WAGMDL00008110	WAGMDL00008111
WAGMDL00008112	WAGMDL00008113
WAGMDL00008119	WAGMDL00008123
WAGMDL00008128	WAGMDL00008132
WAGMDL00010887	WAGMDL00010887
WAGMDL00010925	WAGMDL00010925
WAGMDL00010926	WAGMDL00010926
WAGMDL00010927	WAGMDL00010927
WAGMDL00010928	WAGMDL00010928

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00014995	WAGMDL00014996
WAGMDL00015007	WAGMDL00015015
WAGMDL00015159	WAGMDL00015161
WAGMDL00021425	WAGMDL00021427
WAGMDL00032660	WAGMDL00032662
WAGMDL00034591	WAGMDL00034592
WAGMDL00035669	WAGMDL00035670
WAGMDL00035671	WAGMDL00035683
WAGMDL00037074	WAGMDL00037075
WAGMDL00037093	WAGMDL00037093
WAGMDL00037094	WAGMDL00037094
WAGMDL00037521	WAGMDL00037522
WAGMDL00037523	WAGMDL00037554
WAGMDL00039510	WAGMDL00039511
WAGMDL00039512	WAGMDL00039513
WAGMDL00039524	WAGMDL00039524
WAGMDL00039525	WAGMDL00039525
WAGMDL00039526	WAGMDL00039526
WAGMDL00039527	WAGMDL00039527
WAGMDL00042520	WAGMDL00042523
WAGMDL00044765	WAGMDL00044766
WAGMDL00047953	WAGMDL00047956
WAGMDL00047976	WAGMDL00047980
WAGMDL00049160	WAGMDL00049161
WAGMDL00049389	WAGMDL00049397
WAGMDL00053882	WAGMDL00053883
WAGMDL00058489	WAGMDL00058492
WAGMDL00060486	WAGMDL00060488
WAGMDL00066685	WAGMDL00066686
WAGMDL00071582	WAGMDL00071584
WAGMDL00077015	WAGMDL00077015
WAGMDL00077016	WAGMDL00077023
WAGMDL00092708	WAGMDL00092709
WAGMDL00092961	WAGMDL00092963
WAGMDL00094628	WAGMDL00094629
WAGMDL00094759	WAGMDL00094760
WAGMDL00095316	WAGMDL00095316
WAGMDL00095317	WAGMDL00095336
WAGMDL00099892	WAGMDL00099895

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00101703	WAGMDL00101706
WAGMDL00101723	WAGMDL00101732
WAGMDL00102390	WAGMDL00102392
WAGMDL00104845	WAGMDL00104850
WAGMDL00106996	WAGMDL00106998
WAGMDL00107162	WAGMDL00107163
WAGMDL00107267	WAGMDL00107271
WAGMDL00107473	WAGMDL00107474
WAGMDL00107532	WAGMDL00107533
WAGMDL00107538	WAGMDL00107542
WAGMDL00107557	WAGMDL00107564
WAGMDL00108983	WAGMDL00109002
WAGMDL00109238	WAGMDL00109245
WAGMDL00113042	WAGMDL00113043
WAGMDL00113808	WAGMDL00113810
WAGMDL00119539	WAGMDL00119539
WAGMDL00119542	WAGMDL00119542
WAGMDL00128847	WAGMDL00128850
WAGMDL00129432	WAGMDL00129436
WAGMDL00183443	WAGMDL00183443
WAGMDL00183444	WAGMDL00183446
WAGMDL00183798	WAGMDL00183798
WAGMDL00232750	WAGMDL00232752
WAGMDL00237263	WAGMDL00237264
WAGMDL00237698	WAGMDL00237698
WAGMDL00238576	WAGMDL00238577
WAGMDL00242055	WAGMDL00242057
WAGMDL00245768	WAGMDL00245768
WAGMDL00245769	WAGMDL00245769
WAGMDL00245867	WAGMDL00245920
WAGMDL00246016	WAGMDL00246016
WAGMDL00246284	WAGMDL00246285
WAGMDL00250426	WAGMDL00250426
WAGMDL00250427	WAGMDL00250439
WAGMDL00250440	WAGMDL00250443
WAGMDL00250444	WAGMDL00250455
WAGMDL00254645	WAGMDL00254648
WAGMDL00254649	WAGMDL00254649
WAGMDL00254921	WAGMDL00254929
WAGMDL00286244	WAGMDL00286244

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00286425	WAGMDL00286425
WAGMDL00289026	WAGMDL00289030
WAGMDL00289031	WAGMDL00289035
WAGMDL00289036	WAGMDL00289039
WAGMDL00289040	WAGMDL00289044
WAGMDL00289045	WAGMDL00289049
WAGMDL00289050	WAGMDL00289053
WAGMDL00289054	WAGMDL00289057
WAGMDL00289068	WAGMDL00289178
WAGMDL00289436	WAGMDL00289439
WAGMDL00289450	WAGMDL00289453
WAGMDL00293631	WAGMDL00293631
WAGMDL00302174	WAGMDL00302174
WAGMDL00302958	WAGMDL00302959
WAGMDL00303055	WAGMDL00303055
WAGMDL00303056	WAGMDL00303057
WAGMDL00303305	WAGMDL00303305
WAGMDL00303383	WAGMDL00303407
WAGMDL00305149	WAGMDL00305154
WAGMDL00308327	WAGMDL00308349
WAGMDL00309417	WAGMDL00309419
WAGMDL00311235	WAGMDL00311236
WAGMDL00311410	WAGMDL00311410
WAGMDL00311411	WAGMDL00311411
WAGMDL00316593	WAGMDL00316593
WAGMDL00316594	WAGMDL00316594
WAGMDL00316595	WAGMDL00316595
WAGMDL00316596	WAGMDL00316596
WAGMDL00316597	WAGMDL00316597
WAGMDL00316600	WAGMDL00316600
WAGMDL00317093	WAGMDL00317094
WAGMDL00319129	WAGMDL00319129
WAGMDL00325129	WAGMDL00325129
WAGMDL00325170	WAGMDL00325171
WAGMDL00325172	WAGMDL00325186
WAGMDL00325187	WAGMDL00325191
WAGMDL00325368	WAGMDL00325368
WAGMDL00358471	WAGMDL00358473
WAGMDL00370894	WAGMDL00370895
WAGMDL00371292	WAGMDL00371301

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00379420	WAGMDL00379420
WAGMDL00386743	WAGMDL00386745
WAGMDL00387624	WAGMDL00387624
WAGMDL00387625	WAGMDL00387628
WAGMDL00387629	WAGMDL00387629
WAGMDL00387630	WAGMDL00387630
WAGMDL00387631	WAGMDL00387631
WAGMDL00387632	WAGMDL00387632
WAGMDL00387633	WAGMDL00387634
WAGMDL00387635	WAGMDL00387637
WAGMDL00387638	WAGMDL00387640
WAGMDL00387641	WAGMDL00387641
WAGMDL00387642	WAGMDL00387650
WAGMDL00387651	WAGMDL00387652
WAGMDL00387653	WAGMDL00387707
WAGMDL00387708	WAGMDL00387974
WAGMDL00387975	WAGMDL00387982
WAGMDL00390035	WAGMDL00390036
WAGMDL00390037	WAGMDL00390719
WAGMDL00390720	WAGMDL00390721
WAGMDL00390722	WAGMDL00392427
WAGMDL00392428	WAGMDL00392429
WAGMDL00392430	WAGMDL00393620
WAGMDL00393621	WAGMDL00393623
WAGMDL00393624	WAGMDL00394498
WAGMDL00394499	WAGMDL00394500
WAGMDL00394501	WAGMDL00395015
WAGMDL00395016	WAGMDL00395017
WAGMDL00395018	WAGMDL00395802
WAGMDL00395803	WAGMDL00395804
WAGMDL00395805	WAGMDL00395922
WAGMDL00395923	WAGMDL00395936
WAGMDL00395957	WAGMDL00395964
WAGMDL00395965	WAGMDL00396033
WAGMDL00396034	WAGMDL00396132
WAGMDL00396133	WAGMDL00396134
WAGMDL00396135	WAGMDL00397030
WAGMDL00397031	WAGMDL00397032
WAGMDL00397033	WAGMDL00400341
WAGMDL00400357	WAGMDL00400357

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00400358	WAGMDL00400358
WAGMDL00400359	WAGMDL00400359
WAGMDL00400360	WAGMDL00400360
WAGMDL00400361	WAGMDL00400364
WAGMDL00400365	WAGMDL00400366
WAGMDL00406060	WAGMDL00406064
WAGMDL00407144	WAGMDL00407145
WAGMDL00407476	WAGMDL00407477
WAGMDL00409988	WAGMDL00409994
WAGMDL00414048	WAGMDL00414049
WAGMDL00414254	WAGMDL00414259
WAGMDL00414785	WAGMDL00414787
WAGMDL00415194	WAGMDL00415195
WAGMDL00415257	WAGMDL00415258
WAGMDL00415348	WAGMDL00415350
WAGMDL00418516	WAGMDL00418521
WAGMDL00426251	WAGMDL00426254
WAGMDL00426289	WAGMDL00426293
WAGMDL00436802	WAGMDL00436802
WAGMDL00442094	WAGMDL00442097
WAGMDL00444056	WAGMDL00444058
WAGMDL00477975	WAGMDL00477985
WAGMDL00489370	WAGMDL00489371
WAGMDL00490963	WAGMDL00490978
WAGMDL00490979	WAGMDL00490979
WAGMDL00491251	WAGMDL00491258
WAGMDL00491343	WAGMDL00491344
WAGMDL00491896	WAGMDL00491912
WAGMDL00491961	WAGMDL00491966
WAGMDL00491998	WAGMDL00492000
WAGMDL00492038	WAGMDL00492043
WAGMDL00492067	WAGMDL00492069
WAGMDL00492070	WAGMDL00492072
WAGMDL00492076	WAGMDL00492081
WAGMDL00492130	WAGMDL00492131
WAGMDL00492132	WAGMDL00492149
WAGMDL00492169	WAGMDL00492169
WAGMDL00492171	WAGMDL00492171
WAGMDL00492378	WAGMDL00492380
WAGMDL00492562	WAGMDL00492574

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00492580	WAGMDL00492580
WAGMDL00492626	WAGMDL00492639
WAGMDL00493670	WAGMDL00493678
WAGMDL00493683	WAGMDL00493687
WAGMDL00493688	WAGMDL00493691
WAGMDL00493694	WAGMDL00493718
WAGMDL00493719	WAGMDL00493722
WAGMDL00499183	WAGMDL00499187
WAGMDL00502008	WAGMDL00502009
WAGMDL00528179	WAGMDL00528180
WAGMDL00574824	WAGMDL00574824
WAGMDL00575612	WAGMDL00575613
WAGMDL00576348	WAGMDL00576352
WAGMDL00576457	WAGMDL00576457
WAGMDL00577118	WAGMDL00577118
WAGMDL00580316	WAGMDL00580318
WAGMDL00589682	WAGMDL00589683
WAGMDL00589684	WAGMDL00589690
WAGMDL00615151	WAGMDL00615153
WAGMDL00615165	WAGMDL00615165
WAGMDL00624503	WAGMDL00624509
WAGMDL00624527	WAGMDL00624532
WAGMDL00657563	WAGMDL00657566
WAGMDL00658202	WAGMDL00658216
WAGMDL00658227	WAGMDL00658227
WAGMDL00658246	WAGMDL00658248
WAGMDL00658782	WAGMDL00658789
WAGMDL00659076	WAGMDL00659078
WAGMDL00659270	WAGMDL00659272
WAGMDL00659801	WAGMDL00659801
WAGMDL00659802	WAGMDL00659827
WAGMDL00659828	WAGMDL00659856
WAGMDL00660329	WAGMDL00660329
WAGMDL00660331	WAGMDL00660337
WAGMDL00667936	WAGMDL00667937
WAGMDL00667938	WAGMDL00667943
WAGMDL00673706	WAGMDL00673722
WAGMDL00674124	WAGMDL00674124
WAGMDL00674277	WAGMDL00674279
WAGMDL00674280	WAGMDL00674281

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00674283	WAGMDL00674306
WAGMDL00674321	WAGMDL00674345
WAGMDL00674550	WAGMDL00674623
WAGMDL00677965	WAGMDL00677965
WAGMDL00698150	WAGMDL00698150
WAGMDL00698296	WAGMDL00698297
WAGMDL00700161	WAGMDL00700161
WAGMDL00700240	WAGMDL00700241
WAGMDL00705318	WAGMDL00705320
WAGMDL00705321	WAGMDL00705322
WAGMDL00707883	WAGMDL00707914
WAGMDL00709395	WAGMDL00709397
WAGMDL00709507	WAGMDL00709558
WAGMDL00710201	WAGMDL00710214
WAGMDL00749381	WAGMDL00749407
WAGMDL00751821	WAGMDL00751821
WAGMDL00751822	WAGMDL00751823
WAGMDL00751871	WAGMDL00751872
WAGMDL00752212	WAGMDL00752213
WAGMDL00753975	WAGMDL00753995
WAGMDL00755129	WAGMDL00755147
WAGMDL00757148	WAGMDL00757163
WAGMDL00757172	WAGMDL00757187
WAGMDL00757193	WAGMDL00757211
WAGMDL00757245	WAGMDL00757246
WAGMDL00757247	WAGMDL00757247
WAGMDL00757249	WAGMDL00757249
WAGMDL00757255	WAGMDL00757275
WAGMDL00757284	WAGMDL00757289
WAGMDL00757290	WAGMDL00757293
WAGMDL00757312	WAGMDL00757313
WAGMDL00757316	WAGMDL00757317
WAGMDL00757499	WAGMDL00757510
WAGMDL00757511	WAGMDL00757513
WAGMDL00757514	WAGMDL00757525
WAGMDL00757540	WAGMDL00757548
WAGMDL00757549	WAGMDL00757568
WAGMDL00757569	WAGMDL00757570
WAGMDL00757585	WAGMDL00757589
WAGMDL00757590	WAGMDL00757595

Appendix B
Documents Received - Bates Stamped Documents

Bates Stamped Documents

From	To
WAGMDL00757596	WAGMDL00757597
WAGMDL00757759	WAGMDL00757761
WAGMDL00757762	WAGMDL00757773
WAGMDL00757776	WAGMDL00757784
WAGMDL00757788	WAGMDL00757788
WAGMDL00771984	WAGMDL00771984
WAGMDL00772007	WAGMDL00772009
WAGMDL00772212	WAGMDL00772212
WAGMDL00772216	WAGMDL00772519
WAGMDL00772526	WAGMDL00772526
WAGMDL00772547	WAGMDL00772548
WAGMDL00772807	WAGMDL00772808
WAGMDL00772969	WAGMDL00772970
WAGMDL00772972	WAGMDL00772973
WAGMDL00773061	WAGMDL00773061
WAGMDL00773087	WAGMDL00773087
WAGMDL00773283	WAGMDL00773284
WAGMDL00773289	WAGMDL00773290
WAGMDL00773309	WAGMDL00773310
WAGMDL00773512	WAGMDL00773513
WAGMDL00773522	WAGMDL00773523
WAGMDL00773628	WAGMDL00773629
WAGMDL00773644	WAGMDL00773644
WAGMDL00773659	WAGMDL00773660
WAGMDL00773662	WAGMDL00773662
WAGMDL00773663	WAGMDL00773663
WAGMDL00773791	WAGMDL00773792
WAGMDL00773801	WAGMDL00773801
WAGMDL00773822	WAGMDL00773823
WAGMDL00773926	WAGMDL00773926
WAGMDL00774217	WAGMDL00774217
WAGMDL00777158	WAGMDL00777160

In RE National Prescription Opiate Litigation
Case No. 1:17-MD-2804
U.S. District Court for the Northern District of Ohio, Eastern Division

Appendix B
Documents Received - Non-Bates Stamped Documents

Reports
Expert Analysis: Lacey R. Keller dated April 15, 2019
Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 (and Errata to p. 35)
Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, dated April 3, 2019
Second Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, dated April 15, 2019
Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances, Prepared by James E. Rafalski, dated April 15, 2019
Expert Report of Dr. Stephen W. Schondelmeyer, dated April 15, 2019
Examination of Compliance Standards for Opioid Manufacturers and Distributors, Prepared by Dr. Seth B. Whitelaw, dated April 15, 2019
G. Caleb Alexander, MD, MS, Expert Witness Report, Submitted March 25, 2019
Expert Report of Jane C. Ballantyne, dated March 25, 2019
Expert Report and Appendices Pertinent to the Opioid MDL: David T. Courtwright, Ph.D., dated March 21, 2019
Expert Report of David Cutler, dated March 25, 2019
Report of David D. Egilman MD, MPH, dated March 25, 2019
Expert Report of Jonathan Gruber, dated March 25, 2019
Expert Report of David Kessler, M.D., dated March 25, 2019
Katherine Keyes Expert Witness Report, dated March 25, 2019
Expert Report of Anna Lembke, M.D., dated March 25, 2019
Expert Report of Jeffrey B. Liebman, dated March 25, 2019
Report of Professor Thomas McGuire Regarding Public Nuisance, dated March 25, 2019
Expert Report of Professor Thomas McGuire - Damages to Bellwethers, dated March 25, 2019
Expert Report of Ted Miller, dated March 25, 2019
Expert Report of Theodore Parran, dated March 25, 2019
Expert Report of Matthew Perri III, BS Pharm, Ph.D., RPh, dated March 25, 2019
Expert Report of Professor Meredith Rosenthal, dated March 25, 2019
Expert Report of Mark A. Schumacher, M.D., Ph.D., dated March 25, 2019
Scott L. Wexelblatt, MD Expert Report, dated March 25, 2019
Expert Report of Nancy K. Young, Ph.D., dated March 25, 2019
Expert Analysis - Addendum: Lacey R. Keller dated May 11, 2019
Expert Analysis - Errata Sheet: Lacey R. Keller dated May 11, 2019
Supplemental Report of the Examination of Compliance Standards for Opioid Manufacturers and Distributors, Prepared by Dr. Seth B. Whitelaw, dated May 10, 2019
Expert Report of Robert L. Brunner, dated May 10, 2019
Expert Report of William S. Choi, Ph.D., dated May 10, 2019
Expert Report of Dr. Anupam B. Jena, MD, PhD, dated May 10, 2019
Expert Report of John J. MacDonald III, dated May 10, 2019
Expert Report of Louis J. Milione, dated May 10, 2019
Expert Report of Krista Tongring, dated May 10, 2019
Expert Report of Dennis Wichern, dated May 10, 2019
Expert Report Errata Pages of Robert L. Brunner, dated May 21, 2019 and Map Screenshots

Appendix B
Documents Received - Non-Bates Stamped Documents

Legal Documents

In Re National Prescription Opiate Litigation: Corrected Second Amended Complaint and Jury Demand, filed May 29, 2018
In Re National Prescription Opiate Litigation: Cardinal Health Inc.'s Objections and Responses to Plaintiffs' First Combined Discovery Requests, dated July 31, 2018
In Re National Prescription Opiate Litigation: Cardinal Health Inc.'s First Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests, dated November 30, 2018
In Re National Prescription Opiate Litigation: Defendants Walgreen Co. and Walgreen Eastern Co.'s Second Supplemental Responses to Plaintiffs' "(First) Combined Discovery Requests", dated February 19, 2019
In Re National Prescription Opiate Litigation: Plaintiffs' Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs, dated January 25, 2019
In Re National Prescription Opiate Litigation: Plaintiffs' Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs, dated January 11, 2019
In Re National Prescription Opiate Litigation: Defendants Walgreen Co. and Walgreen Eastern Co.'s Second Amended Objections and Responses to Plaintiffs'First Set of Interrogatories, dated March 4, 2019
Walgreen Co. v. Drug Enforcement Administration , Brief of Petitioner, filed December 26, 2012
Walgreen Co. v. Drug Enforcement Administration , Corrected Initial Brief for Respondents, filed February 13, 2013
Walgreen Co. v. Drug Enforcement Administration , Joint Appendix: JA-1 TO JA-216, filed February 21, 2013
Walgreen Co. v. Drug Enforcement Administration , Reply Brief of Petitioner, filed February 21, 2013
Walgreen Co. v. Drug Enforcement Administration,Oral Arguments Hearing, March 21, 2013
Masters Pharm., Inc. v. Drug Enf't Admin. , 861 F.3d 206, 216-17 (D.C. Cir. 2017).

Public Sources

Drug Enforcement Administration, Congressional Budget Submissions for Fiscal Years 2008 through 2020

February 2015 GAO Report to Congressional Requesters: Drug Shortages – Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved

June 2015 GAO Report to Congressional Requesters: Prescription Drugs – More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access

June 2016 Statement of Diana C. Maurer: Drug Enforcement Administration – Additional Actions Needed to Address Prior GAO Recommendations
Southwood Pharmaceuticals, Inc.; Revocation of Registration, filed July 3, 2007

"Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," Prepared for The Kaiser Family Foundation by The Health Strategies Consultancy LLC, March 2005

Fact Sheet: Prescription Drug Monitoring Programs: April 2011

John B. McKinlay, Ph.D., *et al.;* Effects of Patient Medication Requests on Physician Prescribing Behavior: Results of a Factorial Experiment; Med Care; Published April 2014
McKesson Corp, Form 10-K, for the fiscal year ended March 31, 2007

Appendix B
Documents Received - Non-Bates Stamped Documents

Public Sources
Walgreen Co. Form 10-K, for the fiscal year ended August 31, 2000
Walgreen Co. Form 10-K, for the fiscal year ended August 31, 2004
Walgreen Co. Form 10-K, for the fiscal year ended August 31, 2010
Walgreen Co. Form 10-K, for the fiscal year ended August 31, 2012
Walgreen Co. Form 10-K, for the fiscal year ended August 31, 2013
Walgreens Boots Alliance, Inc., Form 10-K, for the fiscal year ended August 31, 2015
Walgreens Boots Alliance, Inc., Form 10-K, for the fiscal year ended August 31, 2018
AMA Physician Specialty Groups and Codes
Rigg, K. et al."Prescription Drug Abuse & Diversion:The Role of the Pain Clinic."J Drug issues. 2010; 40(3)

Hyperlinked Sources
http://nymag.com/news/intelligencer/topic/57770/
http:www.deadiversion.usdoj.gov/chem_prog/susp.htm
https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk
https://web.archive.org/web/20060615060708/http://www.dea.gov/pubs/cngrtest/ct033006.html
https://web.archive.org/web/20130328192938/
https://www.about-addiction.com/little-known-facts-about-the-history-of-hydrocodone/
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=007337
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=016194
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=040330
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=085106
https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-opioid-epidemic-factsheet.pdf
https://www.chicagotribune.com/business/ct-walgreen-completes-merger-0101-biz-20141231-story.html
https://www.chicagotribune.com/news/ct-xpm-2006-08-16-0608160333-story.html
https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf
https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf
https://www.congress.gov/bill/114th-congress/house-bill/471
https://www.crainscleveland.com/article/20061109/FREE/61109008/tops-stores-to-close
https://www.dea.gov/sites/default/files/2018-07/1999-2003%20p%2091-118.pdf
https://www.dea.gov/sites/default/files/2018-07/2003-2008%20p%20118-153.pdf
https://www.dea.gov/sites/default/files/2018-07/2009-2013%20p%20153-179.pdf
https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm
https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
https://www.deadiversion.usdoj.gov/arcos/handbook/section1.htm
https://www.deadiversion.usdoj.gov/arcos/index.html#background
https://www.deadiversion.usdoj.gov/drug_chem_info/buprenorphine.pdf
https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf
https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf
https://www.deadiversion.usdoj.gov/drug_chem_info/methadone/methadone.pdf
https://www.deadiversion.usdoj.gov/drug_chem_info/oxycodone/oxycodone.pdf
https://www.deadiversion.usdoj.gov/drugreg/categories.htm
https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm
https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm
https://www.deadiversion.usdoj.gov/pubs/presentations/stermidcpgov09.pdf
https://www.deadiversion.usdoj.gov/quotas/quota_apps.htm
https://www.deadiversion.usdoj.gov/quotas/year_end/index.html

Appendix B
Documents Received - Non-Bates Stamped Documents

Hyperlinked Sources
https://www.deadiversion.usdoj.gov/schedules/index.html
https://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm
https://www.deaecom.gov/
https://www.govinfo.gov/content/pkg/CHRG-109hhrg25958/html/CHRG-109hhrg25958.htm
https://www.judiciary.senate.gov/meetings/06/22/2016/oversight-of-the-drug-enforcement-administration
https://www.justice.gov/file/1144616/download
https://www.law.cornell.edu/uscode/text/21/823
https://www.ncbi.nlm.nih.gov/books/NBK232111/
https://www.nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html
https://www.nytimes.com/2005/10/24/technology/pharmacies-endorse-crackdown-on-fraud.html
https://www.ohio-demographics.com/counties_by_population.
https://www.ohnd.uscourts.gov/mdl-2804
https://www.thedailybeast.com/dea-secretly-oks-killer-quantities-of-oxy-and-morphine
https://www.walgreens.com/locator/walgreens-2495+sandy+point+rd-palm+harbor-fl-34685/id=12885
https://www.walgreens.com/locator/walgreens-411+s+mason+rd-katy-tx-77450/id=4696
https://www.walgreens.com/locator/walgreens-5411+leavitt+rd-lorain-oh-44053/id=6574
https://www.walgreens.com/locator/walgreens-7420+state+road+54-new+port+richey-fl-34653/id=5857
https://www.walgreens.com/topic/about/history/ourpast.jsp
https://www.washingtonpost.com/investigations/who-is-joe-rannazzisi-the-dea-man-who-fought-the-drug-companies-and-lost/2017/10/15/c3ac4b0e-b02e-11e7-be94-fabb0f1e9ffb_story.html?utm_term=.4ddd873dc510
https://www.washingtonpost.com/opinions/the-real-history-of-the-dea-and-opioids/2017/12/01/6ab9d194-d5f7-11e7-9ad9-ca0619edfa05_story.html?utm_term=.5366af41f6ca

Other Non-Bates Stamped Sources
GPS_084_71_USC022_mkt_def_APR2018_cleaned_2_21.csv
Order to Show Cause and Immediate Suspension of Registration Sent to Walgreen Co., dated September 13, 2012

Deposition Transcripts and Exhibits
Deposition of Eric Stahmann, October 16, 2018 and Exhibits
Deposition of Steven Mills, November 8, 2018 and Exhibits
Deposition of Patricia Daugherty, November 15, 2018 and Exhibits
Deposition of Stephen Bamberg, December 14, 2018 and Exhibits
Deposition of Edward Kaleta, December 18, 2018 and Exhibits
Deposition of Douglas Peterson, December 20, 2018 and Exhibits
Deposition of Mike Bleser, December 20, 2018 and Exhibits

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Rex Swords, December 21, 2018 and Exhibits
Deposition of Wayne Bancroft, January 10, 2019 and Exhibits
Deposition of Tomson George, January 14, 2019 and Exhibits
Deposition of Edward Lanzetti, January 14, 2019 and Exhibits
Deposition of Denny Murray, Jr., January 15, 2019 and Exhibits
Deposition of Laurie Zaccaro, January 16, 2019 and Exhibits
Deposition of Christopher Domzalski, January 17, 2019 and Exhibits
Deposition of John Merritello, January 18, 2019 and Exhibits
Deposition of Tasha Polster, January 23, 2019 and Exhibits
Deposition of Jamie Whited II, January 23, 2019 and Exhibits
Deposition of Jennifer Diebert, January 24, 2019 and Exhibits
Deposition of Barbara Martin, January 25, 2019 and Exhibits
Deposition of Christopher Dymon, January 25, 2019 and Exhibits
Deposition of Deborah Bish, February 1, 2019 and Exhibits
Deposition of William Hunter, February 12, 2019 and Exhibits
Deposition of Demetra Ashley, March 15, 2019 and Exhibits
Deposition of Keith Martin, April 3, 2019 and Exhibits
Deposition of Stacy Harper-Avilla, April 11, 2019 and Exhibits
Deposition of Joseph Rannazzisi, April 26, 2019 and Exhibits
Deposition of Sean Barnes, January 21, 2019 and Exhibits
Deposition of Sean Barnes, October 22, 2018 and Exhibits
Deposition of Stephen Mays, October 24, 2018 and Exhibits
Deposition of Stephen Mays, February 8, 2019 and Exhibits
Deposition of Kyle Wright, February 28, 2019 and Exhibits
Deposition of Kyle Wright, March 4, 2019 and Exhibits
Deposition of Christopher Zimmerman, August 3, 2018 and Exhibits
Deposition of Christopher Zimmerman, February 8, 2019 and Exhibits
Deposition of Edward Bratton, November 30, 2018 and Exhibits
Deposition of Edward Bratton, December 16, 2018 and Exhibits (Errata Filed March 5, 2019)
Deposition of Thomas Prevoznik, April 17, 2019 and Exhibits
Deposition of Thomas Prevoznik, April 18, 2019 and Exhibits
Deposition of Michael Cochrane, January 15, 2019
Deposition of Jay Spellman, December 19, 2018
Deposition of Eric Brantley, November 27, 2018
Deposition of Raymond Carney, October 16, 2018
Deposition of Christopher Forst, January 22, 2019
Deposition of Mark Hartman, November 15, 2018
Deposition of Jennifer Norris, August 7, 2018
Deposition of Steve Reardon, November 30, 2018
Deposition of James Tsipakis, December 13, 2018
Deposition of June Howard, April 25, 2019

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Michele Dempsey, March 8, 2019
Deposition of Matthew Perri, April 23, 2019
Deposition of Aaron Burtner, January 17, 2019
Deposition of Al Paonessa, February 7, 2019
Deposition of Alan Must, March 14, 2019
Deposition of Allisyn Leppla, January 15, 2019
Deposition of Amanda Stephens Hogan, January 25, 2019
Deposition of Amy Propatier, November 29, 2018
Deposition of Andrea Bucher, January 14, 2019
Deposition of Andrew Boyer, January 15, 2019
Deposition of Andrew Palmer, January 22, 2019
Deposition of Angelo Calvillo, February 8, 2019
Deposition of Ann Berkey, December 13, 2018
Deposition of Anna Lembke, April 24, 2019
Deposition of Anne Connell-Freund, January 24, 2019
Deposition of Anthony Mihelich, January 11, 2019
Deposition of Anthony Mollica, January 4, 2019
Deposition of April Vince, December 13, 2018
Deposition of Ariyapadi Krishnaraj, November 28, 2018
Deposition of Arthur Morelli, January 17, 2019
Deposition of Barrett Woomer, January 25, 2019
Deposition of Bill Brandt, February 14, 2019
Deposition of Blaine Snider, November 8, 2018
Deposition of Bonnie New, February 12, 2019
Deposition of Brad Gessner, December 3, 2018
Deposition of Brandy Carney, January 16, 2019
Deposition of Brian Lortie, January 22, 2019
Deposition of Brian Lortie, January 23, 2019
Deposition of Brian Lortie, March 27, 2019
Deposition of Brian Munroe, March 19, 2019
Deposition of Brian Nelsen, December 19, 2018
Deposition of Brian Nelsen, January 24, 2019
Deposition of Brian Witte, January 24, 2019
Deposition of Bruce Colligen, January 22, 2019
Deposition of Bruce Gundy, November 7, 2018
Deposition of Bruce Moskovitz, November 13, 2018
Deposition of Bruce Moskovitz, November 14, 2018
Deposition of Bruce Ritchie, January 25, 2019
Deposition of Burt Rosen, January 16, 2019
Deposition of Calvin Williams, December 5, 2018
Deposition of Calvin Williams, March 29, 2019

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Candace Harbauer, February 19, 2019
Deposition of Carla Cartwright, January 17, 2019
Deposition of Carol Marchione, January 18, 2019
Deposition of Carolyn Stevenson, December 18, 2018
Deposition of Cassi Baker, January 11, 2019
Deposition of Catherine Jackson, January 7, 2019
Deposition of Cathy Stewart, December 11, 2018
Deposition of Ceila Weber, January 25, 2019
Deposition of Chad Ducote, November 16, 2018
Deposition of Chad Garner, November 14, 2018
Deposition of Charles Brown, November 5, 2018
Deposition of Charles Twigg, January 8, 2019
Deposition of Cheri Walter, February 19, 2019
Deposition of Chris Lanctot, October 10, 2018
Deposition of Christina Delos Reyes, February 8, 2019
Deposition of Christopher Bauch, January 22, 2019
Deposition of Christopher Belli, December 20, 2018
Deposition of Christopher Cabot, November 2, 2018
Deposition of Christopher Kippes, January 18, 2019
Deposition of Christopher Murray, August 3, 2018
Deposition of Christopher Murray, February 21, 2019
Deposition of Chrstine Baeder, January 24, 2019
Deposition of Claire Kaspar, January 15, 2019
Deposition of Clarence Tucker, January 10, 2019
Deposition of Colleen Craven, February 6, 2019
Deposition of Colleen McGinn, December 14, 2018
Deposition of Colleen McGinn, December 14, 2018
Deposition of Corrine Gillenkirk, January 16, 2019
Deposition of Cory Swaisgood, January 23, 2019
Deposition of Craig Baranski, July 12, 2018
Deposition of Craig Schiavo, January 17, 2019
Deposition of Curtis Wright, December 19, 2018
Deposition of Cynthia Condodina, January 9, 2019
Deposition of Cynthia Weiskittel, November 13, 2018
Deposition of Darin Cecil, February 6, 2019
Deposition of Darin Kearns, December 5, 2018
Deposition of David Brennan, January 24, 2019
Deposition of David Carroll, August 8, 2018
Deposition of David Courtwright, April 25, 2019
Deposition of David Cutler, April 26, 2019
Deposition of David Cutler, April 27, 2019

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of David Egilman, April 25, 2019
Deposition of David Egilman, April 26, 2019
Deposition of David Graziano, August 15, 2018
Deposition of David Gretick, December 7, 2018
Deposition of David Gustin, August 17, 2018
Deposition of David Kessler, April 25, 2019
Deposition of David Kessler, April 26, 2019
Deposition of David Lin, December 20, 2018
Deposition of David May, August 4, 2018
Deposition of David Merriman, January 8, 2019
Deposition of David Myers, December 13, 2018
Deposition of Dean Vanelli, January 16, 2019
Deposition of Debbie Hodges, January 11, 2019
Deposition of Deborah Bearer, January 8, 2019
Deposition of Deborah Forkas, January 23, 2019
Deposition of Deborah Watkins, October 9, 2018
Deposition of Debra Chase, January 4, 2019
Deposition of Demir Bingol, January 17, 2019
Deposition of Derek Siegle, January 23, 2019
Deposition of DeWayne Benson, January 22, 2019
Deposition of Diane Miller-Dawson, December 12, 2018
Deposition of Diane Miller-Dawson, January 17, 2019
Deposition of Donald Gerome, March 22, 2019
Deposition of Donald Gerome, November 14, 2018
Deposition of Donald Kyle, March 14, 2019
Deposition of Donald Morse, December 13, 2018
Deposition of Donald Walker, January 10, 2019
Deposition of Donald Wharton, November 14, 2018
Deposition of Donna Skoda, August 14, 2018
Deposition of Doug Yu-Deh Wang, December 18, 2018
Deposition of Douglas Boothe, January 17, 2019
Deposition of Douglas Emma, January 17, 2019
Deposition of Douglas Smith, November 16, 2018
Deposition of Eduardo Romero, November 19, 2018
Deposition of Edward Hazewski, October 25, 2018
Deposition of Egdilio Morales, January 23, 2019
Deposition of Eileen Spaulding, February 5, 2019
Deposition of Elizabeth Garcia, December 14, 2018
Deposition of Elizabeth Tatum, December 11, 2018
Deposition of Ellen Wilson, January 24, 2019
Deposition of Emily Hall, January 22, 2019
Deposition of Eric Cherveny, November 9, 2018

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Eric Griffin, January 23, 2019
Deposition of Eric Hutzell, January 8, 2019
Deposition of Erin Cox, January 17, 2019
Deposition of Eugene Cavacini, January 25, 2019
Deposition of Eugene Tommasi, December 18, 2018
Deposition of Evan Horowitz, January 3, 2019
Deposition of Farid Sabet, January 28, 2019
Deposition of Frank Devlin, January 10, 2019
Deposition of Frank Mashett, January 10, 2019
Deposition of Fred Bencivengo, January 22, 2019
Deposition of Gabriel Weissman, January 17, 2019
Deposition of Gary Boggs, January 17, 2019
Deposition of Gary Boggs, January 18, 2019
Deposition of Gary Boggs, March 12, 2018
Deposition of Gary Gingell, January 23, 2019
Deposition of Gary Gingell, January 25, 2019
Deposition of Gary Gingell, March 28, 2019
Deposition of Gary Gingell, November 20, 2018
Deposition of Gary Guenther, October 16, 2018
Deposition of Gary Henschen, March 16, 2019
Deposition of Gary Hilliard, January 10, 2019
Deposition of Gary Millikan, January 11, 2019
Deposition of Gary Thalacker, January 18, 2019
Deposition of Gary Vorsanger, December 5, 2018
Deposition of Gary Vorsanger, December 6, 2018
Deposition of George Caleb Alexander, April 26, 2019
Deposition of George Chapman, January 9, 2019
Deposition of George Chunderlik, January 16, 2019
Deposition of George Euson, November 27, 2018
Deposition of George Euson, November 28, 2018
Deposition of George Saffold, February 8, 2019
Deposition of George Sterbenz, October 17, 2018
Deposition of George Stevenson, February 15, 2019
Deposition of Gerald Craig, January 11, 2019
Deposition of Gertrude Kass, March 29, 2019
Deposition of Gertrude Wilms, August 13, 2018
Deposition of Gilberto Quintero, December 6, 2018
Deposition of Ginger Collier, January 8, 2019
Deposition of Greg Cordek, December 13, 2018
Deposition of Gregory Beam, January 15, 2019
Deposition of Gregory Carlson, January 8, 2019
Deposition of Gregory Hall, December 19, 2018

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Greta Johnson, January 15, 2019
Deposition of Heidi Gullett, December 14, 2018
Deposition of Henry John Mortelliti, January 23, 2019
Deposition of Holly Woods, January 7, 2019
Deposition of Holly Woods, September 27, 2018
Deposition of Hugh M. O'Neill, March 13, 2019
Deposition of Hugh Shannon, January 15, 2019
Deposition of Hugh Shannon, January 24, 2019
Deposition of Hugh Shannon, March 19, 2019
Deposition of Hylton Baker, December 19, 2018
Deposition of J. David Haddox, April 12, 2019
Deposition of J. David Haddox, February 8, 2019
Deposition of Jack Crowley, January 10, 2019
Deposition of Jackie Pollard, November 30, 2018
Deposition of James Doroz, January 23, 2019
Deposition of James Gatt, December 20, 2018
Deposition of James Gutierrez, January 31, 2019
Deposition of James Gutierrez, January 31, 2019
Deposition of James Hardy, January 17, 2019
Deposition of James Rausch, November 16, 2018
Deposition of James Schoen, February 27, 2019
Deposition of Jane Williams, December 12, 2018
Deposition of Janet Getzey Hart, January 30, 2019
Deposition of Janet Getzey Hart, January 31, 2019
Deposition of Janet Koch, December 13, 2018
Deposition of Jason Briscoe, December 6, 2018
Deposition of Jeannette Barrett, November 2, 2018
Deposition of Jeff Abernathy, November 15, 2018
Deposition of Jeffrey Kilper, February 6, 2019
Deposition of Jeffrey Peacock, January 30, 2019
Deposition of Jeffrey Sturmi, November 15, 2018
Deposition of Jennifer Altier, August 2, 2018
Deposition of Jennifer Hawkins, February 28, 2019
Deposition of Jill Strang, January 3, 2019
Deposition of Jinping McCormick, January 9, 2019
Deposition of Joan Papp, February 5, 2019
Deposition of Joel Saper, January 11, 2019
Deposition of John Adams, January 30, 2019
Deposition of John Gans, March 5, 2019
Deposition of John Gillies, February 7, 2019
Deposition of John Gillies, February 8, 2019
Deposition of John Hassler, January 17, 2019

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of John Hassler, November 16, 2018
Deposition of John Prince, January 30, 2019
Deposition of John Prince, March 29, 2019
Deposition of John Saros, January 22, 2019
Deposition of Jolynn Coleman, December 13, 2018
Deposition of Jonathan Gruber, April 25, 2019
Deposition of Joseph Ganley, July 27, 2018
Deposition of Joseph Hennessy, January 8, 2019
Deposition of Joseph Millward, December 20, 2018
Deposition of Joseph Nanni, January 10, 2019
Deposition of Joseph Natko, October 9, 2018
Deposition of Joseph Tomkiewicz, November 28, 2018
Deposition of Joyce DelGaudio, January 23, 2019
Deposition of Julie Barnes, December 3, 2018
Deposition of Julie Snyder, November 2, 2018
Deposition of Kanitha Burns, November 29, 2018
Deposition of Karen Butler, March 13, 2019
Deposition of Karen Harper, January 15, 2019
Deposition of Kate Neely, January 8, 2019
Deposition of Kathe Sackler, April 1, 2019
Deposition of Katherine Keyes, April 29, 2019
Deposition of Keith Frost, January 15, 2019
Deposition of Keith Miller, December 18, 2018
Deposition of Kelly Baker, January 24, 2019
Deposition of Kenneth Ball, November 7, 2018
Deposition of Kevin Becker, January 24, 2019
Deposition of Kevin Kreutzer, November 27, 2018
Deposition of Kevin Mitchell, January 16, 2019
Deposition of Kevin Vorderstrasse, December 5, 2018
Deposition of Kevin Webb, January 17, 2019
Deposition of Kevin Webb, January 17, 2019
Deposition of Kevin Webb, January 18, 2019
Deposition of Kim Howenstein, January 10, 2019
Deposition of Kimberly Anna-Soisson, January 24, 2019
Deposition of Kimberly Byers, August 7, 2018
Deposition of Kimberly Deem-Eshleman, November 15, 2018
Deposition of Kimberly Patton, January 22, 2019
Deposition of Kirk Dumont, January 18, 2019
Deposition of Kirk Harbauer, February 27, 2019
Deposition of Kristin Vitanza-Squires, December 20, 2018
Deposition of Kristine Fidler, July 19, 2018
Deposition of Kristy Spruell, January 16, 2019

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Larry Ringgold, January 24, 2019
Deposition of Larry Romaine, January 10, 2019
Deposition of Latoya Laroche, February 1, 2019
Deposition of Laura Sippial, January 22, 2019
Deposition of Lee Ann Storey, December 10, 2018
Deposition of Linda Kitlinski, January 15, 2019
Deposition of Lisa Cardetti, January 10, 2019
Deposition of Lisa Kohler, July 31, 2018
Deposition of Lisa Walker, December 4, 2018
Deposition of Lori Baker-Stella, March 29, 2019
Deposition of Louis LaMarca, March 22, 2019
Deposition of Lynn Phillips, February 12, 2019
Deposition of Marcelino Guerreiro, April 3, 2019
Deposition of Margaret Feltz, January 15, 2019
Deposition of Margaret June Carr, December 21, 2018
Deposition of Margaret Keenan, December 12, 2018
Deposition of Margaret Keenan, January 18, 2019
Deposition of Marian Wood, January 24, 2019
Deposition of Mark Geraci, April 4, 2019
Deposition of Mark Nicastro, December 6, 2018
Deposition of Mark Potter, January 18, 2019
Deposition of Mark Schumacher, April 23, 2019
Deposition of Mark Vernazza, November 20, 2018
Deposition of Martha Newman, March 20, 2019
Deposition of Martha Vachon Davis, April 11, 2019
Deposition of Mary Applegate, January 23, 2019
Deposition of Mary Applegate, March 28, 2019
Deposition of Mary Woods, January 10, 2019
Deposition of Mary Woods, January 9, 2019
Deposition of Matthew Baeppler, January 17, 2019
Deposition of Matthew Day, January 4, 2019
Deposition of Matthew Paolino, December 5, 2018
Deposition of Matthew Perri, April 24, 2019
Deposition of Matthew Rogos, February 22, 2019
Deposition of Maurice Mulcahy, February 5, 2019
Deposition of Melinda Burt, October 30, 2018
Deposition of Merle Gordon, July 19, 2018
Deposition of Michael Amen, January 25, 2019
Deposition of Michael Bianco, January 18, 2019
Deposition of Michael Bishop, January 9, 2019
Deposition of Michael Clarke, December 7, 2018
Deposition of Michael Connelly, November 7, 2018

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Michael DiBello, February 19, 2019
Deposition of Michael Dorsey, January 8, 2019
Deposition of Michael Morreale, January 10, 2019
Deposition of Michael Oriente, July 19, 2018
Deposition of Michael Perfetto, December 18, 2018
Deposition of Michael Shearer, December 13, 2018
Deposition of Michael Wessler, January 9, 2019
Deposition of Michele Dempsey, January 22, 2019
Deposition of Miranda Johnson, December 12, 2018
Deposition of Molly Leckler, November 19, 2018
Deposition of Nancy Baran, December 11, 2018
Deposition of Nathalie Leitch, January 22, 2019
Deposition of Nathan Elkins, November 14, 2018
Deposition of Nathan Hartle, August 1, 2018
Deposition of Nathan Hartle, July 31, 2018
Deposition of Nawang Kunga, January 24, 2019
Deposition of Neil Shusterman, January 17, 2019
Deposition of Neil Shusterman, January 18, 2019
Deposition of Nicholas Rausch, November 16, 2018
Deposition of Nicole Carlton, November 27, 2018
Deposition of Nikki Seckinger, December 12, 2018
Deposition of Nycole West, December 14, 2018
Deposition of Pamela Bennett, January 16, 2019
Deposition of Pamela Bennett, March 1, 2019
Deposition of Pamela Hinkle, January 24, 2019
Deposition of Patricia Cooney, January 24, 2019
Deposition of Patricia Rideout, January 11, 2019
Deposition of Patricia VanderMeersch, December 18, 2018
Deposition of Patricia Williams, December 13, 2018
Deposition of Patrick Cochrane, January 24, 2019
Deposition of Patrick Cochrane, January 25, 2019
Deposition of Patrick Fourteau, February 22, 2019
Deposition of Patrick Gillespie, January 8, 2019
Deposition of Patrick Leonard, January 31, 2019
Deposition of Patrick Leonard, March 27, 2019
Deposition of Patsy Little, December 14, 2018
Deposition of Paul Andrew Pyfer, February 20, 2019
Deposition of Paul Campanelli, March 21, 2019
Deposition of Paul Coplan, January 18, 2019
Deposition of Persis Sosiak, November 2, 2018
Deposition of Peter Ratycz, December 21, 2018
Deposition of Philip Cramer, November 19, 2018

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Philip Cramer, November 20, 2018
Deposition of Philip Cramer, November 20, 2018
Deposition of Philip Raub, February 19, 2019
Deposition of Rachel Parikh, December 7, 2018
Deposition of Rachelle Galant, January 15, 2019
Deposition of Ralph Piatak, January 14, 2019
Deposition of Ramona Sullins, January 4, 2019
Deposition of Randy Heiser, February 19, 2019
Deposition of Randy Spokane, December 5, 2018
Deposition of Rich Ryu, January 18, 2019
Deposition of Richard Chapman, December 18, 2018
Deposition of Richard Fanelli, December 6, 2018
Deposition of Richard Fanelli, December 7, 2018
Deposition of Richard Fanelli, December 7, 2018
Deposition of Richard Sackler, March 7, 2019
Deposition of Richard Sackler, March 8, 2019
Deposition of Richard Weiler, January 25, 2019
Deposition of Rita Norton, January 9, 2019
Deposition of Robert Barto, January 30, 2019
Deposition of Robert Brown, December 3, 2018
Deposition of Robert Kaiko, November 28, 2018
Deposition of Robert Keith, January 23, 2019
Deposition of Robert McClune, January 25, 2019
Deposition of Ron Kuntz, January 23, 2019
Deposition of Ron Kuntz, January 24, 2019
Deposition of Ronald Jackson, December 18, 2018
Deposition of Ronald Link, December 11, 2018
Deposition of Ronald Wickline, November 13, 2018
Deposition of Roxanne McGregor-Beck, January 17, 2019
Deposition of Roxanne Reed, January 10, 2019
Deposition of Russell Gasdia, January 15, 2019
Deposition of Russell Gasdia, November 28, 2018
Deposition of Sabrina Solis, January 10, 2019
Deposition of Sally Riddle, December 6, 2018
Deposition of Sarita Thapar, January 10, 2019
Deposition of Scott Moran, December 20, 2018
Deposition of Scott Moran, March 27, 2019
Deposition of Scott Osiecki, January 18, 2019
Deposition of Scott Tomsky, March 15, 2019
Deposition of Scott Villarreal, December 4, 2018
Deposition of Scott Wexelblatt, April 24, 2019
Deposition of Sergio Tejeda, April 2, 2019

Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Shane Barker, November 28, 2018
Deposition of Sharon Cole Juhan, March 13, 2019
Deposition of Sharon Hartman, November 29, 2018
Deposition of Sharon Sobol Jordan, February 7, 2019
Deposition of Shaun Abreu, December 13, 2018
Deposition of Shauna Helfrich, January 10, 2019
Deposition of Shelley Patena, February 6, 2019
Deposition of Sherri Hinkle, January 25, 2019
Deposition of Shirlene Justus, July 13, 2018
Deposition of Sophia Novack, January 9, 2019
Deposition of Stacey Beckhardt, February 1, 2019
Deposition of Stacy Chick, December 13, 2018
Deposition of Stephan Kaufhold, October 26, 2018
Deposition of Stephen Fricker, December 4, 2018
Deposition of Stephen Lawrence, January 4, 2019
Deposition of Stephen Macrides, March 15, 2019
Deposition of Stephen Seid, December 12, 2018
Deposition of Stephen Seid, December 12, 2018
Deposition of Stephen Seid, December 13, 2018
Deposition of Steve Perch, October 18, 2018
Deposition of Steven Becker, December 19, 2018
Deposition of Susan Jolliff, December 13, 2018
Deposition of Susanne Hiland, January 22, 2019
Deposition of Susanne Hiland, January 23, 2019
Deposition of Tara Chapman, December 6, 2018
Deposition of Terrance Terifay, January 11, 2019
Deposition of Terrence Allan, December 17, 2018
Deposition of Terrence Dugger, January 23, 2019
Deposition of Terri Nataline, December 13, 2018
Deposition of Terry Albanese, January 4, 2019
Deposition of Thomas Convery, January 23, 2019
Deposition of Thomas Gilson, January 14, 2019
Deposition of Thomas Gilson, January 22, 2019
Deposition of Thomas McConnell, December 11, 2018
Deposition of Thomas McConnell, December 12, 2018
Deposition of Thomas McDonald, December 7, 2018
Deposition of Thomas McGuire, April 23, 2019
Deposition of Thomas Moffatt, January 15, 2019
Deposition of Thomas Napoli, January 17, 2019
Deposition of Thomas Schoen, September 5, 2018
Deposition of Thomas Udicious, January 24, 2019
Deposition of Tiffany Rowley-Kilper, February 9, 2019

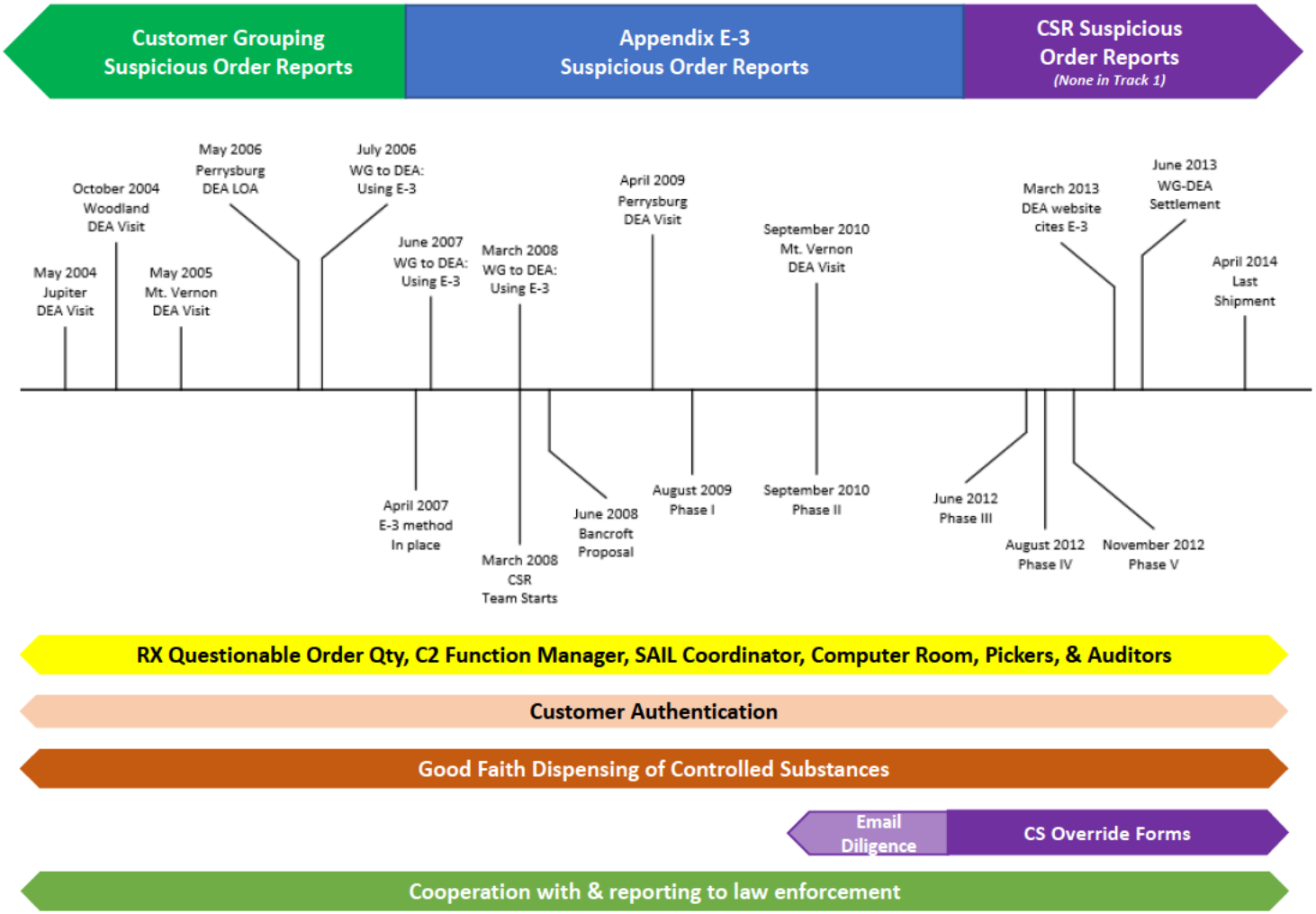
Appendix B
Documents Received - Non-Bates Stamped Documents

Deposition Transcripts and Exhibits
Deposition of Tina Steffanie-Oak, March 11, 2019
Deposition of Tom Nameth, January 7, 2019
Deposition of Tonya Block, November 14, 2018
Deposition of Tracey Norton, January 16, 2019
Deposition of Tracey Norton, January 17, 2019
Deposition of Tracy Jonas, November 15, 2018
Deposition of Trevor McAleer, January 10, 2019
Deposition of Valerie Kaisen, January 18, 2019
Deposition of Vicki Mangus, December 11, 2018
Deposition of Victor Borelli, November 29, 2018
Deposition of Victor Perez, April 4, 2019
Deposition of Walter Parfejewiec, November 8, 2018
Deposition of Walter Wayne Durr, January 22, 2019
Deposition of Wendy Weaver, January 16, 2019
Deposition of William de Gutierrez-Mahoney, November 28, 2018
Deposition of William Denihan, January 30, 2019
Deposition of William Harper, December 11, 2018
Deposition of William Ratliff, December 19, 2018
Deposition of William Verosky, December 7, 2018
Deposition of Craig McCann, May 9, 2019 and Exhibits
Deposition of Craig McCann, May 10, 2019 and Exhibits
Deposition of James Rafalski, May 13, 2019 and Exhibits
Deposition of James Rafalski, May 14, 2019 and Exhibits
Deposition of Joseph Rannazzisi, May 15, 2019 and Exhibit 8
Deposition of Seth Whitelaw, May 16, 2019 and Exhibits
Deposition of Seth Whitelaw, May 17, 2019 and Exhibits
Deposition of Thomas Prevoznik, May 17, 2019 and Exhibits
Deposition of Lori Baker-Stella, March 29, 2019 and Exhibits
Deposition of John Prince, March 29, 2019
Deposition of Patrick Leonard, March 27, 2019

Appendix C

Name	Deposition Date(s)	Company/Role	Tenure at Company	Relevant Titles
Steven Mills	11/8/2018	Walgreens	2005-Present	Member of the Pharmacy Integrity Group
Douglas Peterson	12/20/2018	Walgreens	2003-Present	IT Manager in Logistics
Edward Lanzetti	1/14/2019	Walgreens	1992-2018	Loss Prevention Specialist, Asset Protection Manager, Lead Director - Asset Protection
Laurie Zaccaro	1/16/2019	Walgreens	2006-Present	Asset Protection Manager
John Merritello	1/18/2019	Walgreens	1977-Present	Program Manager - Retail Systems/Marketing Systems/Inventory System
Jennifer Diebert	1/24/2019	Walgreens	2003-Present	SAIL/C2 Coordinator and Supervisor - Perrysburg Distribution Center
Deborah Bish	2/1/2019	Walgreens	2006-2013	C-II Function Manager - Perrysburg Distribution Center
Demetra Ashley	3/15/2019	DEA	1988-2018	Diversion Investigator, Group Supervisor, Staff Coordinator, Associate Section Chief, Diversion Program Manager, Senior Executive
Stacy Harper-Avilla	4/11/2019	DEA	2008-2018	Unit Chief - United Nations Reporting and Quota Section
Joseph Rannazzisi	4/26/2019 and 5/15/2019	DEA	2005-2015	Deputy Assistant Administrator of the DEA's Office of Diversion Control
Kyle Wright	2/28/2019 and 3/4/2019	DEA	1995-2005	Diversion Investigator - Dallas Field Division
Christopher Zimmerman	30(b)(6): 8/3/2018 Personal Capacity: 2/8/2019	AmerisourceBergen	1990-Present	Senior Vice President - Chief Compliance Officer, Senior Vice President - Corporate Security and Regulatory Affairs
Edward Bratton Personal Capacity and 30(b)(6)	Personal Capacity: 11/30/2018 30(b)(6): 12/16/2018	Walgreens	2013-Present	Manager of Pharmaceutical Integrity - Southern Operations
Thomas Prevoznik Personal Capacity and 30(b)(6)	Personal Capacity: 4/17/2019 30(b)(6): 4/18/2019 Additional Dep: 5/17/2019	DEA	2017-Present	Associate Section Chief in Pharmaceutical Investigations, Acting Section Chief of Pharmaceutical Investigations
Wayne Bancroft	1/10/2019	Walgreens	2004-Present	Senior Qualitative Analyst
Patricia Daugherty	11/15/2018	Walgreens	2002-2011; 2013-Present	Clinical Operations Pharmacy Manager, Network Audit and Compliance Manager/Director, Manager Pharmaceutical Integrity
Mike Bleser	12/20/2018	Walgreens	1993-Present	Vice President - Generic Prescription Purchasing and Prescription Supply Chain
Patrick Leonard	3/27/2019	Akron PD	1997-Present	Narcotics Detective - Akron Police Department
Seth Whitelaw	5/16/2019 and 5/17/2019	Expert	N/A	Plaintiffs' Expert
James Rafalski	5/13/2019 and 5/14/2019	Expert	N/A	Plaintiffs' Expert
Craig McCann	5/9/2019 and 5/10/2019	Expert	N/A	Plaintiffs' Expert

Appendix D


Customer Grouping Suspicious Order Reports
Appendix E-3 Suspicious Order Reports
CSR Suspicious Order Reports
(None in Track 1)
May 2004 Jupiter DEA Visit
October 2004 Woodland DEA Visit
May 2005 Mt. Vernon DEA Visit
May 2006 Perrysburg DEA LOA
July 2006 WG to DEA: Using E-3
April 2007 E-3 method In place
June 2007 WG to DEA: Using E-3
March 2008 WG to DEA: Using E-3
March 2008 CSR Team Starts
June 2008 Bancroft Proposal
April 2009 Perrysburg DEA Visit
August 2009 Phase I
September 2010 Mt. Vernon DEA Visit
September 2010 Phase II
June 2012 Phase III
August 2012 Phase IV
November 2012 Phase V
March 2013 DEA website cites E-3
June 2013 WG-DEA Settlement
April 2014 Last Shipment
RX Questionable Order Qty, C2 Function Manager, SAIL Coordinator, Computer Room, Pickers, & Auditors
Customer Authentication
Good Faith Dispensing of Controlled Substances
Email Diligence
CS Override Forms
Cooperation with & reporting to law enforcement

Appendix E